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NATIONAL HEART TRANSPLANTATION STUDY

VOLUME 1.

HISTORICAL PERSPECTIVES
METHODOLOGY

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NATIONAL HEART TRANSPLANTATION STUDY

VOLUME 1.

HISTORICAL PERSPECTIVES

CHAPTER 1. THE ANATOMY OF A STUDY: THE NATIONAL HEART TRANSPLANTATION STUDY, FOOLHARDY OR FARSIGHTED?

CHAPTER 2. RENAL TRANSPLANTATION: THE PROTOTYPE

CHAPTER 3. HEART TRANSPLANTATION: A BOLD EXPERIMENT, NOW REALITY

CHAPTER 4. IMMUNOSUPPRESSIVE AGENTS AND TECHNIQUES: THE ACHILLES' HEEL OF ORGAN TRANSPLANTATION

METHODOLOGY

CHAPTER 5. THE HEART TRANSPLANT RECIPIENT SURVEY

CHAPTER 6. THE ABSTRACTION OF MEDICAL AND HOSPITAL RECORDS

CHAPTER 7. THE SURVEYS OF FAMILY AND HOUSEHOLD MEMBERS

CHAPTER 8. THE PARTICIPATING HEART TRANSPLANT CENTERS

CHAPTER 9. A DESCRIPTIVE ANALYSIS OF HEART TRANSPLANT RECIPIENTS

VOLUME 2.

THE NEED FOR HEART TRANSPLANTATION

CHAPTER 10. THE NEED FOR HEART TRANSPLANTATION: AN OVERVIEW

CHAPTER 11. MORBIDITY AS AN INDICATOR OF THE NEED FOR HEART TRANSPLANTATION

CHAPTER 12. MORTALITY AS AN INDICATOR OF THE NEED FOR HEART TRANSPLANTATION

CHAPTER 13. THE NEED FOR HEART TRANSPLANTATION AMONG CURRENT MEDICARE BENEFICIARIES

CHAPTER 14. A SYNTHESIS OF THE ESTIMATES OF THE NEED FOR HEART TRANSPLANTATION

THE AVAILABILITY OF DONOR ORGANS

CHAPTER 15. AN OVERVIEW OF ORGAN DONOR ISSUES

CHAPTER 16. PROBLEMS IN THE IDENTIFICATION OF POTENTIAL DONORS: MISCONCEPTIONS AND FALLACIES ASSOCIATED WITH DONOR CARDS

CHAPTER 17. POTENTIAL ORGAN DONOR AVAILABILITY: RESULTS OF AN ATTITUDE SURVEY

CHAPTER 18. AN ANALYSIS OF IN-HOSPITAL DEATHS AS AN INDICATOR OF DONOR AVAILABILITY

CHAPTER 19. DONOR AVAILABILITY: AN ANALYSIS OF ORGAN PROCUREMENT PROGRAM DATA

VOLUME 3.

SURVIVAL

CHAPTER 20. AN OVERVIEW OF SURVIVAL ANALYSIS ISSUES

CHAPTER 21. SURVIVAL OF HEART TRANSPLANT RECIPIENTS

CHAPTER 22. A COMPARISON OF THE SURVIVAL OF RECIPIENTS AND NONRECIPIENTS OF HEART TRANSPLANTS

QUALITY OF LIFE

CHAPTER 23. AN OVERVIEW OF QUALITY OF LIFE ASSESSMENT AMONG HEART TRANSPLANT RECIPIENTS

CHAPTER 24. THE WORK STATUS OF LIVING HEART TRANSPLANT RECIPIENTS

CHAPTER 25. AN ANALYSIS OF THE OBJECTIVE AND SUBJECTIVE QUALITY OF LIFE OF LIVING HEART TRANSPLANT RECIPIENTS

CHAPTER 26. A COMPARATIVE ANALYSIS OF QUALITY OF LIFE: HEART TRANSPLANTATION, KIDNEY TRANSPLANTATION, KIDNEY DIALYSIS, AND THE GENERAL POPULATION

COST OF HEART TRANSPLANTATION

CHAPTER 27. AN OVERVIEW OF THE COST ANALYSES

CHAPTER 28. THE MEDICAL COSTS OF HEART TRANSPLANTATION

CHAPTER 29. THE COST-EFFECTIVENESS OF HEART TRANSPLANTATION

CHAPTER 30. AGGREGATE COSTS OF HEART TRANSPLANTATION: SIMULATION MODEL AND RESULTS

VOLUME 4.

LEGAL ISSUES

CHAPTER 31. AN OVERVIEW OF THE LEGAL ISSUES

CHAPTER 32. THE PATIENT AND ENTITLEMENT TO BENEFITS

CHAPTER 33. LEGAL ISSUES SURROUNDING THE DONOR

CHAPTER 34. LEGAL ISSUES SURROUNDING PROVIDERS

ETHICAL DILEMMAS

CHAPTER 35. AN OVERVIEW OF THE ETHICAL ISSUES

CHAPTER 36. SELECTION OF RECIPIENTS FOR CARDIAC TRANSPLANTATION

CHAPTER 37. ETHICAL ISSUES CONCERNING DONORS, RECIPIENTS, AND PROVIDERS IN CARDIAC TRANSPLANTATION

CHAPTER 38. ETHICAL ISSUES IN MACROALLOCATION OF CARDIAC TRANSPLANT

VOLUME 5.

MISCELLANEOUS ISSUES

CHAPTER 39. THE DIFFUSION OF HEART TRANSPLANTATION: RESULTS OF A SURVEY OF HOSPITALS WITH OPEN-HEART SURGERY FACILITIES

CHAPTER 40. SOURCES OF PAYMENT FOR HEART TRANSPLANTATION WITH AN EMPHASIS ON THE ROLE OF PRIVATE INSURERS

CHAPTER 41. AN EXCURSION INTO THE FIELD OF HEALTH CARE TECHNOLOGY ASSESSMENT

CHAPTER 42. EXPERIMENT VERSUS THERAPY: IS THE DILEMMA WORTH THE DEBATE?

CHAPTER 43. THE ARTIFICIAL HEART

CHAPTER 44. LESSONS LEARNED FROM THE END-STAGE RENAL DISEASE EXPERIENCE: THEIR IMPLICATIONS FOR HEART TRANSPLANTATION

CHAPTER 45. A PERSPECTIVE ON HEALTH CARE RESOURCE ALLOCATION AND RATIONING DECISIONS

BIBLIOGRAPHY

CHAPTER 1

THE ANATOMY OF A STUDY: THE NATIONAL HEART TRANSPLANTATION STUDY, FOOLHARDY OR FARSIGHTED?

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A. INTRODUCTION

The National Heart Transplantation Study began amidst controversy. Few studies, in the absence of planning, have been so inextricably and unexpectedly intertwined with the events of the day (Iglehart, 1983a; 1983b). For example, 18 months ago it would have been impossible to anticipate the extent of publicity that organ transplantation has received. This publicity began with Congressional hearings held before the Subcommittee on Investigations and Oversight (Chaired by Congressman Albert R. Gore) of the House of Representatives' Science and Technology Committee in April, 1983, and has continued to this very day.

By the time of the Gore hearings, as they are commonly referred to, the National Heart Transplantation Study had been ongoing for approximately 21 months. The study had originally been scheduled for completion in 18 months. At the time of the hearings, the study was projected to be completed in June, 1984. Had the original project timetable been met, the final report would have been submitted to the Health Care Financing Administration at the time the Gore hearings were being held.

There are many reasons the project was delayed. Some of these are reviewed below along with the events leading up to the inception of the study, the award of the study contract to the Battelle Human Affairs Research Centers by the Health Care Financing Administration (HCFA), as well as the highly publicized and often controversial events surrounding organ transplantation.

Within the scope of an introductory statement such as this, it is impossible to fully recount or adequately reflect on what were the

most significant events. Those that appeared insignificant at first, later proved important. Nonetheless, even amidst the controversial events that surrounded the study, it has been possible to conduct what many view as the most comprehensive assessment of health care technology ever undertaken. Often considered as the prototype of health technology assessment (Knox, 1980), the study has been imbued with a sense of cooperation rarely demonstrated when several parties come together with very diverse interests at stake. On the one hand, patients and physicians have insisted that heart transplantation is a therapeutic rather than an experimental or investigational procedure. They therefore feel that both public and private insurers should be reimbursed for the procedure accordingly. On the other hand, those with administrative responsibility for public and private insurance programs have been hesitant. For example, the Health Care Financing Administration, with administrative authority over the federal Medicare and state Medicaid programs must carefully weigh arguments concerning the disbursement of federal (and state) funds for the payment of costly medical procedures. Private insurers have also proceeded cautiously in making coverage determinations because of the serious financial implications of high cost medical technology.

Not surprisingly, patients, physicians, and policymakers have all expressed uncertainty over the likely success of the National Heart Transplantation Study. Success to patients and physicians means a favorable coverage determination for heart transplantation. Success to government officials and administrators of private insurance companies is marked by a decision that will enable them to function within their budgetary constraints.

Because of these very diverse concerns, the research team at Battelle has made a special effort to approach the issues as objectively as possible. The team had to collect substantial data to assess what were determined to be the key questions. Consequently, the research team's measure of success is quite different from that of patients, physicians, and policymakers. Success in their case, was to complete the study in a manner that would answer the key questions raised by the Health Care Financing Administration. In fact, it is noteworthy that the study team is precluded from making specific policy recommendations to HCFA. While the study results will be used to formulate public policy, the study contract explicitly states that "The Contractor is not to draw policy conclusions based on its analysis. DHHS will perform that function." Therefore, this report contains no specific recommendations on or about what HCFA should do in rendering its coverage determination.

B. THE SHROUD OF CONTROVERSY

Richard Knox, a medical writer with the Boston Globe, published the most exhaustive account of the events leading up to the National Heart Transplantation Study in an article in Science on August 1, 1980 entitled "Heart Transplants: To Pay or Not to Pay." Knox' article was ahead of its time: even the subtitle of the article, "Cardiac Replacement Pushes HHS Into Drafting Policy About Emerging Medical Technology," has proven to be most insightful. The account that follows is based largely on the report of Knox (1980). The events, their sequence, and the persons involved have been verified, to the extent possible, as accurate.

Knox (1980) first noted the historical lack of constraints placed on medical innovations. The prevailing attitude has always been: if it works it should be used irregardless of cost and if the procedure does not produce favorable results it should be discarded. Historically, the Health Care Financing Administration had only to answer these questions in responding to inquiries about and making decisions concerning payment (Towery and Perry, 1981; Roe, 1981; Greenberg and Derzon, 1981): (1) Is it safe?, (2) Is it effective?, and (3) Does it have wide acceptance in the medical community?

Knox suggested "the government has embarked on a new and utterly uncharted course" when Secretary of then Department of Health and Human Services (DHHS), Patricia Roberts Harris, announced on June 12, 1980 that DHHS would require new technologies to pass muster on the basis of their "social consequences" before "financing their wide distribution." In considering heart transplantation, Harris declared that it held a more or less symbolic place in the ranking of therapies with regard to aggressiveness and that it should serve as "the prototype" of technology assessment. Beginning in the fall of 1980 she proclaimed that the department would, in Knox' words, "launch an unprecedentedly broad assessment of the operation and its ramifications." Harris said the study would consider "the patient selection process, the long-term social, economic, and ethical consequences of the procedure, and the potential for national expansion of the heart transplantation procedure."

In reviewing Harris' comments, Knox concluded that "according to the secretary and top HHS officials, this assessment will be a sort of environmental impact statement for medical innovation encompassing

such boundless issues as a new procedure's cost-effectiveness and cost-benefit ratios, its ethical implications and its 'long-term effects on society'." Knox went on to note that, "It will be the first time in the 15-year history of Medicare the government has attempted to define what is meant by the statutory requirement that the program pay only for 'reasonable and necessary' medical care--including such controversy-fraught issues as 'necessary for whom' and 'reasonable under what circumstances'?"

It was estimated that the study would cost nearly $2.0 million and would take about two years. At the time, DHHS staffers were less optimistic saying it would probably "cost more and take longer" (Knox, 1980:570).

According to Harris, DHHS planned to examine the data on the 200 or so transplants performed in the U.S. over the past 11 years and would also follow prospectively patients receiving heart transplants over the next two years. It was implied that while Medicare would support "qualified" patients as part of the study, this action would not bind Medicare to paying for heart transplants in the future. At the time she speculated that the study would be centered at Stanford University Medical Center, the premiere heart transplant center in the world, although other medical centers would be given an opportunity to participate.

Knox (1980) traced the study's legal foundation back to an "...obscure provision of the original 1965 Medicare statute that had to be stretched in a new direction to enable the department to do what it wanted to: fund heart transplants only at a specific institution or two for specified types of patients." Interestingly, DHHS General

Counsel at the time, Joan Z. Bernstein, noted that selective reimbursement provisions were not provided for in the law.

Reflecting on the study, Harris remarked that it was really her idea because there were numerous "unanswered" questions surrounding heart transplantation. She indicated that the department "wants to know how much additional life a heart transplant buys, at what cost, but it also wants to analyze the quality of life posttransplant" (Knox, 1980:570). DHHS officials noted that there were several other issues that must also be addressed, among them (Knox, 1980):

- Characteristics of patients who were selected for transplantation to see if there was any implicit discrimination by social class, education, economic resources, or age.
- What resources were necessary to perform heart transplants well, and whether the operation should be regionalized, which would be unprecedented.
- Prospects for advances in immunosuppression, preservation of donor organs, and the artificial heart as a substitute for or stopgap measure for end-stage heart patients--
any of which could alter the demand and cost sides of the equation.

At the time the study was conceived, a controversial analysis of heart transplantation had been completed by several DHHS staffers including John B. Reiss, Frank Hellinger, and John Burckhardt (see Reiss et al., 1982; Hellinger, 1982). The study estimated the first year costs of a heart transplantation program at $212.2 million to $3.2 billion depending on whether 2,000 or 30,000 transplants were done. Thus, another objective of the study was to examine "all inclusive costs of heart transplantation, including but not limited to medical expenses."

It was also suggested that the DHHS study of heart transplantation would examine potential "trade-offs." As Knox noted: how does a heart transplant compare with other heroic medical care in terms of costs and benefits? He asked, "Does transplantation imply diverting funds from other programs, such as immunization of the elderly against pneumonia?"

Reflecting on the overall objectives of the study, Knox (1980:571) concluded that:

> Obviously an ambitious if not hopelessly broad undertaking the study reflects a once-burned-twice-shy attitude traceable to Medicare's 8 year-old End-Stage Renal Disease program, which was launched without serious consideration of questions such as these.

Heart transplantation was to serve as an example whereby technology diffusion would be regulated by necessity, not choice according to Ruth Hanft, then director of the Office of Health Research, Statistics, and Technology within the Public Health Service. The decision had been to start with percutaneous transluminal coronary angioplasty, but, in her words, heart transplantation could not wait.

Knox (1980) also traced the history of heart transplantation and sought out the reasons why heart transplantation had become such a pressing issue. He noted the first transplant performed by Dr. Christiaan Barnard in Capetown, South Africa and the subsequent landmark developments at Stanford under the direction of Dr. Norman Shumway. In Knox' analysis he commented that Shumway favored the diffusion of heart transplantation but at a "measured rate." But this, according to Knox, "was the rub." In his words, "there has never been a mechanism in this country to regulate the diffusion of

new medical technology once past the strictly investigative stage, other than the skepticism or enthusiasm of the doctors involved." For this reason, and others, Knox (1980) surmised, Congress had set up the National Center for Health Care Technology in 1979 to "serve as an early warning system for new medical technologies."

Ultimately, several noteworthy events took place that made heart transplantation an unavoidable issue. In 1979 DHHS officials discovered that Blue Cross of Northern California, the regional Medicare intermediary, had paid for 23 transplants and 21 post-transplant cases at Stanford since 1973 under the assumption that the procedure was therapeutic and no longer experimental. DHHS attempted to cease payment for heart transplants but was forced to confront the issue in a rather dramatic way. An uninsured patient in need of a heart transplant arrived at Stanford. The university hospital, in the midst of dealing with other financial crises, did not feel it could underwrite the cost of the procedure. Knox (1980:571) reported that "A Stanford attorney told the Los Angeles Herald-Examiner that the man (may be the patient to force the issue)."

DHHS succumbed to the political pressures at hand and decided to pay for this patient as well as others at Stanford on a "tentative" and temporary basis, indicating that it would arrive at a final decision in early 1980.

The decision in November, 1979 to hesitate on the heart transplant issue resulted in considerable controversy within DHHS. Harris sought expert advice from an ad hoc panel of 18 cardiologists and transplant surgeons, convened by the National Heart, Lung, and Blood Institute (NHLBI) at the behest of the National Center for Health Care

Technology. The Panel, according to Knox (1980:571), concluded that it could make no "...generalized or unqualified statement" about the safety, efficacy, and reasonableness of heart transplantation. They did feel, however, that Shumway's program at Stanford met all these criteria.

On January 21, 1980, NHLBI Deputy Director, Peter Frommer, presented DHHS with a memorandum he drafted and had reviewed by the Panel. In the memorandum he recommended that Medicare pay for heart transplants performed at Stanford and other U.S. centers that, according to Knox (1980:572) "...met comparable standards of expertise, resources, and commitment, and for patients who fit the Stanford selection criteria or 'acceptable equivalents'." The memorandum did note "...two dangers which must be forcefully resisted or carefully avoided" including proliferation of other centers not as well-equipped as Stanford and loosening of patient selection criteria (for example, to encompass older patients or those with multiple organ failure). Frommer's memorandum and related documentation is included here as Appendix 1-A.

Frommer, although an advocate of the controlled expansion of heart transplantation, felt that donor heart supply, estimated to be about 1,000 annually, would greatly constrain the overall level of heart transplant activity. In short, he did not feel heart transplantation would become a "runaway technology" (Knox, 1980:572). At the time Frommer predicted that there would be no more than 10 to 20 groups initiating heart transplant programs "for at least the next five years."

Frommer's memorandum was passed on to HCFA as the recommendation of the NCHCT, but the reviews were mixed. Hanft (cited in Knox, 1980:522) told the Center's advisory board that the issue was being addressed too narrowly: "We'll have to face the same series of questions for all transplants including liver, bone, pancreas, lung, and heart-lung, which is within about two years of clinical trial at Stanford."

Harris was equally unsatisfied with the memorandum and recommendations noting that there were many questions left unanswered in the report. Further questions on the memorandum dwelled on the ethical issues surrounding patient selection-- "...how to choose the lucky 250 or 500 or 1000 or 2000 recipients from a potential candidate pool of 15 to 120 times that size" (Knox, 1980:572). Frommer disagreed with the excessive importance these questions appeared to take on noting that "to say that no one should benefit from a technology so scarce and expensive that it can be extended to only a fraction of those who might benefit 'is analogous to arguing that if not everyone can fit into the only lifeboat from a sinking ship, it is unethical for anyone to get in'." (cited in Knox, 1980).

The prevailing patient selection criteria, which according to some were merely indicators of social worth and likely to produce heart transplant candidates that were white, middle-class, males was a most convincing stumbling block. On May 27, 1980 a second Panel convened by Frommer met and in order to get around the patient selection questions, drafted a memorandum that stated: "For purposes of HCFA, these criteria must be stated more generally and exclusively in terms

of enhancing the likelihood of successful medical outcome." A copy of the June 2, 1980 memorandum drafted by Frommer is included as Appendix 1-B.

As the controversy flared within DHHS and between DHHS and the NHLBI, an interesting case arose in Arizona concerning selective reimbursement, the very part of the entire controversy that appeared to be a non-issue. Knox' (1980:575) account of these events is most revealing:

> In early March, Administrative Law Judge Walter McCormies of the Social Security Administration ruled that Medicare must pay a $30,533.68 claim for the heart transplant of Norman E. "Dutch" Tarr, a 50-year old retired Air Force Master Sergeant who lives in Tucson. Tarr was one of the first patients in the heart transplant program set up at the University of Arizona Health Sciences Center by Jack Copeland, a Shumway trainee.
>
> Blue Cross of Arizona, the Medicare intermediary locally, denied the University of Arizona's claim for Tarr's transplant because the operation "is considered experimental or investigational."
>
> Charles E. Buri of the Arizona Attorney General's office countered successfully before Judge McCormies that "experimental" had nothing to do with it. The only test, Buri asserted, was whether a heart transplant was "reasonable and necessary" treatment for Tarr. It didn't hurt Buri's case to have Tarr at the hearing, looking fit nearly a year after his transplant--living proof that the operation was at least "necessary" for him.

As noted by Knox, the fact that Arizona Senators Barry Goldwater and Dennis DeConcini and Congressman Morris Udall were supporters of Norman Tarr, served to illustrate that resource allocation and rationing decisions are difficult to make when confronted with a patient in need. Politicians and non-politicians alike tend to view such arguments as bureaucratic and insensitive.

Knox (1983:1980) concluded his report with characteristically clairvoyant remarks on the funding of heart transplants:

> ...government funds are not the only funds available for heart transplants. Some private insurance companies pay for the operation, as do some but by no means all Blue Cross plans. And, HHS can do nothing about entire towns raising the money to pay for some patient's new heart, just as they used to pay for dialysis in the days before Congress placed that burden on the Medicare trust funds.

Thus, the stage was set for a massive study to review and evaluate heart transplantation. At the time it was recognized that heart transplantation could not be viewed in the abstract and that many of the issues it raised were generic to other health care technologies. Not only was a substantial burden placed on the federal government but private insurers were also later to identify heart transplantation as a key technology in their own coverage policies.

C. THE INTERMEDIATE STEP: FORMULATING AND FUNDING THE STUDY

On June 12, 1980 Secretary Harris announced the decision to exclude heart transplants from Medicare coverage, with the exception of a few patients who had previously been selected for and were awaiting transplants. A notice to this effect was published in the Federal Register on August 6, 1980 (Newman, 1980). This decision, it was clear, was in direct response to the outcome of the Tarr case. At the same time, Harris announced that DHHS would conduct the comprehensive assessment of heart transplantation described above. Rather than conduct an intramural study, DHHS decided in favor of awarding a research contract (not a grant) on the basis of competitive bids.

For the next several months, staff from the Health Care Financing Administration in close collaboration with the staffs from the National Center for Health Care Technology and the National Heart, Lung, and Blood Institute, began to prepare the request for proposals (RFP) required to enable the government to conduct research via the contract mechanism. This is a lengthy process since several clearances and approvals are required before a government agency can issue an RFP for a competitive rather than sole source award (many clearances are also required for the latter as well). These activities culminated with a Federal Register announcement appearing on January 22, 1981 (Newman, 1981) entitled "Medicare Program; Solicitation of Hospitals and Medical Centers to Participate in a Study of Heart Transplants." The summary of the notice as it appeared is as follows:

> SUMMARY. This notice invites hospitals and medical centers to participate in a study of heart transplants to be conducted by HCFA. The purpose of the study is to examine, in general, all aspects of heart transplants, including the scientific, social, economic, and ethical issues, and, in particular, the impact of a possible Medicare decision to pay for heart transplants on the Medicare program, Medicare beneficiaries, and providers of health care. The study will be done in two related parts--the selection and participation of hospitals and medical centers, to which this notice is addressed, and an analysis of pertinent data and issues, to be conducted by an independent contractor.
>
> Hospitals or medical centers selected to participate in this study, under this notice, may be reimbursed for a limited number of heart transplants performed for Medicare beneficiaries during the course of the study. In addition, these institutions will furnish data about heart transplants performed at their facilities and will be reimbursed for the costs of furnishing this information.
>
> This notice contains information about the study, the availability of funds, and the procedures by which interested institutions can communicate their willingness

> to participate in the study. This notice also contains the criteria for the selection of hospitals and medical centers for heart transplant funding.

According to the notice, applications were to be received by 4:30 PM, March 30, 1981.

It is instructive to further review the specific contents and provisions of the January 22, 1981 Federal Register notice because the basic elements of the study, as well as the study procedures, were spelled out clearly. Overall there has been relatively little deviation in the scope of the Study, with the exception of the project timetable. Initially the study was intended to begin approximately in May, 1981 and would be conducted over an 18-month period. The study did not begin until October, 1981 and was completed in August, 1984.

The notice indicated that "Hospitals and medical centers participating in the study will furnish information about heart transplants performed during a period starting no later than January 1, 1975 and continuing through the period of this study. This will include data on the institution's facility and personnel resources, heart donor program, patient selection criteria, transplant and patient care protocols, patient follow-up care, patient survival, cost of establishing and maintaining a heart transplant program, patient charge information, and other similar and related information."

According to the solicitation, institutions could participate in the study in one of two ways--they could only furnish data or they could furnish data and receive reimbursement for some agreed upon number of transplants. It was clear from the notice that the number of institutions to receive payment for heart transplants was finite

and that Medicare trust funds would be used to pay for the procedures. The notice read:

> HCFA will provide payments for qualified hospitals and medical centers for a total of approximately 15 heart transplants performed for Medicare beneficiaries during the study period...The institutions selected will receive payment, in accordance with Medicare regulations, for all inpatient and outpatient care and diagnostic and therapeutic services including physicians' and other medical services, ordinarily furnished during the evaluation, transplantation, and follow-up portions of the heart transplant program.

The Federal Register notice spelled out in detail the institutional selection criteria. These criteria, as they appeared in the notice, are reproduced in Table 1-1. The rationale for the criteria was briefly summarized as follows: "Because of these unusual complexities (i.e., patient selection, expert surgery, patient management, immunosuppression, etc.) and the need for achieving reasonable clinical results with cardiac transplantation, we will be setting forth guidance for the use of institutions in preparing applications and for use in selecting institutions."

The criteria specified in Table 1-1 were developed under the direction of Dr. Peter L. Frommer of the National Heart, Lung, and Blood Institute, with the advice of an advisory group of experts in cardiology, cardiovascular surgery, organ transplantation, and immunology. The criteria were furnished to HCFA by the National Center for Health Care Technology.

The use of an outside panel to advise on various aspects of the study did not cease with the specification of institutional selection criteria. A panel of experts representing the fields of medicine described above were also to:

Table 1-1
Selection Criteria for Institutions Participating In The
National Heart Transplantation Study

(1) The institution must have adequate patient selection criteria.

a. Patient selection criteria are to be based upon both critical medical need for transplantation and maximum likelihood of successful clinical outcome.

b. The institution selects patients that have a very poor prognosis (e.g., less than 10-25 percent likelihood of survival for six months) as a result of poor cardiac functional status.

c. All other medical and surgical therapies have been considered or tried that might be expected to yield improvement and a one-year survival comparable to that of cardiac transplantation.

d. Patient selection criteria give consideration to those factors that are recognized at the present time as exerting an adverse influence on the outcome after cardiac transplantation (see below).

(2) The institution must have adequate patient management plans and protocols that include the following:

a. Detailed plans for the therapeutic and evaluative procedures for the acute and long-term management of a patient, including commonly encountered complications.

b. The basis for confidence in the proposed therapeutic and evaluative regimen.

c. The logistics of the plans for patient management and evaluation during the waiting and immediate post-discharge, as well as in-hospital, phases of the program.

d. The logistics of the plans for the long-term management and evaluation including education of the patient and liaison with the patient's permanent physician.

Table 1-1 (Continued)
Selection Criteria for Institutions Participating In The
National Heart Transplantation Study

(3) The institution must have made a sufficient commitment of resources and planning to the heart transplant program. Indications of such commitment could include the following:

a. Commitment of the institution to the heart transplant program is at all levels and broadly evident throughout the institution. (A cardiac transplantation program requires a major commitment of resources. These may intermittently include many other departments as well as the principal sponsoring departments.)

b. There are both the expertise and the commitment for participation in the medical, surgical, and other relevant areas, particularly cardiology, cardiovascular surgery, anesthesiology, immunology, infectious diseases, nursing, neurology/neurosurgery, and social services. In most of these areas, individual persons need to be identified to achieve an identifiable and stable transplant team.

c. The component teams are integrated into a comprehensive team with clearly defined leadership and corresponding responsibility.

d. The institution has an active clinical organ transplantation program involving immunosuppressive techniques and the results of that program. (In the absence of such an active clinical organ transplant program, the institution may have great difficulty in showing that the necessary expertise will be available and logistically feasible.)

e. There is an active cardiovascular, medical, and surgical program. (General indicators of this would be a minimum of 500 cardiac catheterizations and coronary arteriograms annually, with the ability and willingness to do such procedures on an emergency basis, and a surgical group that has demonstrated low mortality rates in an active open heart surgical program involving at least 250 procedures a year.) The surgical team responsible for transplantation must be an identified, stable group.

f. The anesthesia service is prepared to develop a team for transplantation that will also be available at all times.

Table 1-1 (Continued)
Selection Criteria for Institutions Participating In The
National Heart Transplantation Study

g. The infectious diseases service has both professional skills and the laboratory resources that are needed to discover, identify, and manage a whole range of organisms, many of which are uncommonly encountered in the usual infectious diseases laboratory.

h. The nursing service is prepared to develop a team or teams trained not only in hemodynamic support of the patient, but also in the special problems of managing immunosuppressed patients.

i. Pathology resources are available for studying and promptly reporting the pathological responses to transplantation.

j. A neurology or neurosurgery group is available for the donor selection procedures for objective clinical decision on brain death.

k. Adequate social service resources are available.

l. There is a clearly assigned and knowledgeable legal officer familiar with transplantation laws and regulations.

m. Adequate logistical plans exist for organ procurement meeting legal and ethical criteria, as well as yielding viable transplantable organs in reasonable numbers.

SOURCE: Federal Register Vol. 46, No. 14, Pgs. 7072-7074, Thursday, January 22, 1981.

> ...examine written materials submitted by the applicant institutions and may seek additional relevant information as necessary, for example through site visit to the applicant institutions and interviews with relevant persons. The panel of experts will compare the institution's submission against the criteria specified below, in recommending institutions for heart transplant funding. Although each of the four major criteria listed (in Table 1-1) are required, the panel will not necessarily recommend only those institutions that adhere strictly to the sub-criteria identified. It will take into account all evidence set forth by the applicant institution, the facility's overall medical experience, and its experience in cardiac transplantation.

The Panel was equally cautious in stating the implications of their criteria. The notice indicated that:

> These criteria do not necessarily represent our view as to what procedures are essential to assessing safety and efficacy in the performance of cardiac transplantation. However, in our view, they do give us guidance in conducting this study in a responsible manner.

As noted above, not every person with end-stage cardiac disease would be eligible to have his or her heart transplant paid for under the provisions of the study. Most importantly, patients were to be eligible for both Medicare Parts A and B. To qualify for Medicare benefits, a person must be age 65 or over or have been declared disabled for a period of at least two years. Since age in excess of 50-54 years is considered a contraindication to heart transplantation, practically speaking, it is only under this second provision that patients could have their transplant paid for under the study. The Federal Register notice was very specific about patient selection factors. The notice read: "Patient selection criteria give consideration to those factors that are recognized at the present time as exerting an adverse influence on the outcome after cardiac

transplantation." The more specific criteria contained in the notice are reproduced in Table 1-2. These criteria are nearly identical to those in use by most cardiac transplant programs in the U.S. today (Baumgartner et al., 1979; Oyer et al., 1981; 1982; Thomas and Lower, 1978; Reitz and Stinson, 1982; Copeland et al., 1981; Thompson, 1983).

Ultimately 12 institutions applied to participate in the study, and be reimbursed for heart transplants through the Medicare program. Not a single institution agreed to provide data only. Of the institutions that applied, only six met all the study criteria. Thereafter, these six were extended an invitation to participate. These institutions are as follows:

- University of Arizona Health Sciences Center
- Columbia Presbyterian Medical Center
- Medical College of Virginia
- University of Minnesota
- University of Pittsburgh
- Stanford University Medical Center

Each of these institutions subsequently agreed to abide by the terms and conditions of participation. The six have served as the clinical centers in the National Heart Transplantation Study.

As noted above, HCFA planned to select an independent contractor to analyze the data generated during the course of the study. On March 3, 1981 a notice appeared in the Commerce Business Daily announcing the availability of a request for proposals (RFP) to conduct a study on "The Scientific, Social, Economic, and Ethical

Table 1-2
Patient Selection Criteria for the National
Heart Transplantation Study

(1) Advancing age--e.g., beyond the age (normally about 50) at which the individual begins to have diminished capacity to withstand postoperative complications;

(2) Severe pulmonary hypertension as reflected, for example, by a pulmonary artery systolic pressure over 65-70mm Hg and exceeding pulmonary artery wedge pressure by about 40 or more mm Hg, or a calculated pulmonary vascular resistance above approximately 6 Wood units (applicable to orthotopic cardiac transplantation because of the limited work capacity of a normal donor right ventricle);

(3) Irreversible and severe hepatic or renal dysfunction (because of the likelihood of exacerbation early postoperatively and because of interference with immunosuppressive regimens);

(4) Active systemic infection (because of the likelihood of exacerbation with initiation of immunosuppression);

(5) Any other systemic disease considered likely to limit or preclude survival and rehabilitation after transplantation;

(6) A history of behavior pattern or psychiatric illness likely to interfere significantly with compliance with a disciplined medical regimen (because a lifelong medical regimen is necessary, requiring multiple drugs several times a day with serious consequences in the event of their interruption or excessive consumption);

(7) Recent and unresolved pulmonary infarction or pulmonary roentgenographic evidence of abnormalities of unclear etiology (because of the likelihood of pulmonary infection or its exacerbation with initiation of immunosuppression under such circumstances);

(8) Insulin-requiring diabetes mellitus (because of exacerbation by chronic corticosteroid therapy);

(9) Symptomatic or documented severe asymptomatic peripheral or cerebrovascular disease (because of observed accelerated progression in some patients after cardiac transplantation and on chronic corticosteroid treatment);

Table 1-2 (Continued)
Patient Selection Criteria for the National
Heart Transplantation Study

(10) Acute peptic ulcer disease (because of the likelihood of early postoperative exacerbation);

(11) The absence of adequate external psychosocial supports for either short or long-term bases (because such support is generally necessary during the inevitable waxing and waning of the clinical status of the patient and for adherence to the lifelong medical regimen).

SOURCE: Federal Register Vol. 46, No. 14, Pgs. 7072-7074, Thursday, January 22, 1981.

Coverage for Heart Transplants." This announcement is reproduced in Table 1-3. The due date for proposals was June 30, 1981.

In response to this notice, a group of researchers under the direction of Dr. Roger W. Evans, met at the Battelle Human Affairs Research Centers in Seattle, Washington on May 26, 1981 to consider the merits of submitting a proposal in response to the announcement of the RFP. Many of the researchers attending the meeting were already engaged in a separate study on kidney dialysis and kidney transplantation, the National Kidney Dialysis and Kidney Transplantation Study, that was also directed by Dr. Evans. This particular solicitation, therefore, offered the Battelle research team a unique opportunity to further their research efforts in health care technology assessment.

A proposal was prepared organized around seven major study components. They included: (1) an epidemiological or need analysis, (2) survival analysis, (3) organ procurement analysis, (4) cost analysis, (5) sociomedical (quality of life analysis), (6) legal analysis, and (7) ethical analysis. A proposal was submitted to the Health Care Financing Administration on the appropriate due date.

On September 30, 1981 Battelle was notified that it had received the contract to conduct the study. The total contract award was $553,607 for a project period of 18 months. The study was to be completed on February 28, 1983.

While there have been some changes in project personnel and project responsibilities, much of the original research team remained intact throughout the study. Table 1-4 identifies the key study components and those persons with primary responsibilities for associated project tasks. In addition, Table 1-5 identifies

Table 1-3
Commerce Business Daily Announcement Concerning
The National Heart Transplantation Study

The Scientific, Social, Economic, and Ethical Coverage for Heart Transplants. The purpose of this solicitation is to analyze the scientific, economic, and ethical consequences of Medicare coverage for heart transplants. The basic issues of the project are the need for heart transplants, the current and future donor availability, the cost of treatment, the quality of life post transplantation and ethical considerations for the patient, the donor, and the government. The data for the analysis will be obtained from selected hospitals performing heart transplants and from a survey of heart transplant recipients. Data from the hospitals will include costs, medical records, and treatment regimens. The survey of the recipients will focus on their medical costs, work history, health status, and psycho-social reactions to transplantation. The forecasting of trends in the event of Medicare coverage for heart transplants will be an important feature of the analysis. Requests for the RFP must be in writing referencing RFP-HCFA-81-ORDS-06/AMG. Approximate date of release is in March.81. No telephone requests will be honored. RFP availability is limited and will be furnished to any requester as supplies permit (058).

Table 1-4
National Heart Transplantation Study Research Team
Task Leaders

PROJECT DIRECTOR:

Roger W. Evans, Ph.D.

STUDY COMPONENTS		TASK LEADER
1.	Need Analysis	Roger W. Evans, Ph.D.
2.	Survival Analysis	John J. Crowley, Ph.D.[1]
3.	Organ Procurement Analysis	Diane L. Manninen, Ph.D.
4.	Cost Analysis	Louis P. Garrison, Jr., Ph.D.
5.	Sociomedical Analysis	Roger W. Evans, Ph.D.
6.	Legal Analysis	Thomas D. Overcast, J.D., Ph.D.
7.	Ethical Analysis	Albert R. Jonsen, Ph.D.[2]

[1]Fred Hutchinson Cancer Research Center, Seattle, Washington

[2]University of California-San Francisco, San Francisco, California

Table 1-5
Associated Project Staff

1. Research Specialists

- Julie Elworth
- L. Gary Hart
- Junichi Yagi

2. Research Assistants

- Lisa Bowen
- Cynthia Livak
- Karen Merrikin
- Judith Raab
- Lair Showalter

3. Computer Programmers

- Anthony Maier
- Jonathan Rodin

4. Secretary

- Millie Gregory

5. Project Consultants

- Christopher R. Blagg
- Bernard Gersh
- Jeffrey Lehman
- John A. Murray
- Gene Pierce
- Steven Schmutte
- Michael Shapiro
- Milton Weinstein

6. Clerk

- Donna McLynne

7. Contracts Administrator

- James L. Richards

Excludes heart transplant center staff (see Chapter 8).

associated project staff including research specialists, research assistants, computer programmers, and project consultants. Also, the original study contract stipulated that a project Technical Review Panel would be selected by HCFA staff to assist in the "technical aspects of the study." The members of this Review Panel and their affiliations are shown in Table 1-6.

Several staff members from HCFA have been associated with the project, usually as Project Officers. The project, logically divided into a demonstration as well as an evaluation component, has always had one government Project Officer for each component. On the demonstration side, Mr. Arne Anderson has been the Project Officer. On the evaluation side, there have been numerous Project Officers. In chronological order they are as follows: Dr. Nancy Greenspan, Dr. Korbin Liu, Dr. Bradford Perry, and Dr. Joel Broida. Transitions between Project Officers have been unusually smooth and little time has been lost in the process.

As with any undertaking the size of the National Heart Transplantation Study, numerous problems were encountered. Many of these nearly defied imaginative solutions. At the outset, it was clear that a great deal of primary data collection would be required to answer all the questions in the RFP. It was unclear, however, at precisely what cost. Given the demands for data placed upon the heart transplant centers, it was necessary to pay them for the staff time required to compile it. Thus, Battelle entered into fixed price subcontracts with each center in August-September, 1983.

Prior to this time, however, a rather lengthy delay (nearly 9 months) occurred during the clearance of data collection forms for the

Table 1-6
Technical Review Panel for the National
Heart Transplantation Study

PANEL MEMBER	AFFILIATION
Marie Blackman, M.D.	Upstate Medical Center
David McKusick	Actuarial Research Corp.
Thomas C. Schelling, Ph.D.	Harvard University
Laurence Tancredi, J.D., M.D.	New York University
Robert L. Wallace, M.D.	Georgetown University
Leroy Walters, Ph.D.	Georgetown University

study by the Office of Management and Budget. This was at least partially due to the fact that the study forms were very lengthy and complicated. The forms were finally cleared in June, 1983 and data collection for the study commenced in September, 1983.

The cost of data collection, as well as various contract modifications that were found desirable, necessitated a request for additional funds from the Health Care Financing Administration. An extended timetable was also needed due to various project delays. After much negotiating, dating back to August, 1982, Battelle was awarded an additional $1.1 million in June, 1983 and granted an extended timetable with the project final report due on August 31, 1984. Thus, the total cost of the study (excluding the heart transplants paid for by Medicare) has been $1.6 million and the total period of performance has been 35 months. As reflected by changes in the study scope and timetable, the study now completed is more comprehensive than originally envisioned.

D. THE TEST OF TIME

Over the course of the National Heart Transplantation Study changes have occurred in both the study and in the events of the day. At the outset of the study few lay people or even medical professionals were aware that heart transplantation was still an area of medical research and practice. Private insurers had not yet realized the implications progress in the field would have for their reimbursement policies. Moreover, Congress showed little interest in the subject. The Health Care Financing Administration seemed alone in exhibiting concern about the subject. HCFA anticipated the complexity of the

issues surrounding heart transplants and realized that the agencies it commonly turned to for assistance in making coverage determinations did not have the resources or the time to carefully examine the very critical issues involved in this particular coverage determination. Even the new National Center for Health Care Technology, a highly controversial and soon to be abolished organization, seemed incapable of helping resolve the apparent problems (Perry and Kalberer, 1980; Perry, 1982a; 1982b; Sun, 1983; Bunker et al., 1982a; 1982b; Relman, 1982).

At the time HEW (now DHHS) decided to do the study, it had other resources that it could have used to address some of the issues surrounding heart transplantation. For example, the Office of Medical Applications of Research (OMAR) could have been consulted and a consensus panel could have been convened to take up the issue. This course of action was not followed, probably because National Institutes of Health consensus development conferences, according to OMAR format, limit their attention to just the medical and scientific issues and do not take into account social, economic, and ethical concerns (Iglehart, 1983b). Still another resource was the Office of Health Research, Statistics, and Technology (now the Office of Health Technology Assessment within the Public Health Service). Again, however, this group traditionally focused on medical and scientific issues. With no "viable" option available, and with the imminent demise of the National Center for Health Care Technology looming ahead, HEW decided to conduct a study. This decision to conduct the research extramurally underscored a major dilemma faced by the Health Care Financing Administration--that it did not have comprehensive

resources to whom it could turn for routine assessment of the complex questions raised by emerging, new, and existing health care technology. Recent interest in organ transplantation and Congressional hearings, in particular, have rekindled interest in the subject outside of HHS as well as inside its various subagencies. Much of this revival of interest in organ transplantation itself can be attributed to a technology, a new immunosuppressive drug--cyclosporine.

DHHS continues to grapple with these newly publicized determinations of medical necessity and appropriate use of technology. In addition, the issues may now be affected by the new prospective payment guidelines. These guidelines may also affect the rate at which new health care technology enters the marketplace and the rate that it is adopted by health care providers (Simborg, 1981; Valdeck, 1983; Thompson, 1983; Lee and Wallace, 1972; Iglehart, 1983c; 1982a; 1982b; Fetter et al., 1980; OTA, 1982; 1983; Anderson and Steinberg, 1984). It could, in effect, have implications for the regionalization of specialty types of medical care. Prospective reimbursement is an interesting development that was not operational at the time the National Heart Transplantation Study began. However, a diagnosis-related grouping (DRG) has been assigned to heart transplantation, although there is no assurance the procedure will be paid for under the Medicare program.

It is apparent that people are more interested in entertaining discussion of the social, ethical, and financial implications of advanced medical technology today than they were in 1980; while open discussions of allocation and rationing are now frequent, actual progress has proceeded slowly (Banta et al., 1981; Evans, 1983a;

1983b; Schwartz and Joskow, 1978; Schelling, 1968; Cochrane, 1971; Schwartz and Aaron, 1984; Fuchs, 1974; Winslow, 1982; Calabresi and Bobbitt, 1978; Englehardt, 1984). Cost-effectiveness and cost-benefit analysis techniques are useful, although imperfect, tools for helping to resolve the complex problems of resource allocation and rationing facing modern medicine and today's society (Weinstein and Stason, 1976; Bunker et al., 1977; Weinstein and Stason, 1977; Weinstein, et al., 1980; OTA, 1980; Warner and Luce, 1982; Weinstein, 1983; Vladeck, 1984). Despite overall changes in mood, the medical profession as well as consumers so far have been slow to acclimate to a new reimbursement environment that places increasing emphasis on patient outcomes as the indicator of what public and private insurers are willing to pay for. Medical research itself is likely to be effected by these changes (see Chapter 42).

As predicted at the outset of the study, legal concerns are gaining an increasingly prominent place in medicine. Among the many questions being asked are the following: Under what circumstances might patient selection or reimbursement decisions take on legal implications? Can restrictions be placed on providers of certain types of specialized care? Has the End-Stage Renal Disease program set a precedent that is now nearly inescapable?

Medical ethics, always a specialized interest of a few philosophers and ethicists, has now come into its own as a field of specialization to be reckoned with (Beauchamp and Childress, 1979; Callahan, 1980; Veatch, 1981; Childress, 1982; Gorovitz, 1982; Jonsen et al., 1982; Gorovitz et al., 1983; Bayer et al., 1983; Francoeur, 1983). At the outset of the National Heart Transplantation Study many people who had

heard of ethics thought of it as some obscure medical specialty. That attitude is now changing due in large part to the ethical issues raised by the artificial heart, the Baby Doe cases, and the more than casual interest of the public in organ transplants (De Vries et al., 1984; Woolley, 1984; Galletti, 1984; Strauss, 1984; Hefferman, 1984; Pless, 1983; Weir, 1983; Angell, 1983; Englehardt, 1984).

Medical professionals today are as fragmented on the issues as they were in 1980. The overall mood has changed gradually to increasing recognition of problems heretofore unappreciated. However, the search for a quick-fix is still far more attractive than is the idea of fiscal biting the bullet. But the shortsighted value of "quick fixes" is becoming increasingly evident with the continued growth of a complex armamentarium of medical technology. Questions now concern both saving lives, and when to declare death as an event. A recent Presidential Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (1983) report has explored the merits of insuring an adequate level of health care for the population with the suggestion that increasingly sophisticated and expensive medical technology detracts from this overall goal (see Chapter 38).

Congressional hearings and various meetings have been held to discuss organ transplantation. Table 1-7 is a summary of recent events in organ transplantation beginning with the hearings of the Subcommittee on Investigations and Oversight of the House of Representatives Committee on Science and Technology. The initial hearings focused largely on problems of organ procurement. In particular, they centered on the unique problems of children in need

Table 1-7
Recent Events In Organ Transplantation

April 13-14, 1983	ORGAN TRANSPLANT HEARINGS (CONGRESSMAN GORE)
April 27, 1983	ORGAN TRANSPLANT HEARINGS (CONGRESSMAN GORE)
June 7-9, 1983	SURGEON GENERAL'S WORKSHOP ON SOLID ORGAN PROCUREMENT FOR TRANSPLANTATION: EDUCATING THE PHYSICIAN AND THE PUBLIC
June 20-23, 1983	NIH CONSENSUS DEVELOPMENT CONFERENCE ON LIVER TRANSPLANTATION
July 29, 1983	ORGAN TRANSPLANT HEARINGS (CONGRESSMAN WAXMAN)
September 21-22, 1983	MEETING OF A STEERING COMMITTEE FOR THE FORMATION OF A FEDERATION TO ENCOURAGE ORGAN DONATIONS FOR TRANSPLANTATION (SURGEON GENERAL)
September 22, 1983	FORMATION OF THE AMERICAN COUNCIL ON TRANSPLANTATION
October 17, 1983	HEARINGS ON ORGAN TRANSPLANTS-HR4080 (CONGRESSMAN WAXMAN)
October 20, 1983	HEARINGS ON ORGAN TRANSPLANTATION (SENATOR HATCH)
October 31, 1983	HEARINGS ON ORGAN TRANSPLANTS-HR4080 (CONGRESSMAN WAXMAN)
November 7, 1983	HEARINGS ON FOREIGN NATIONALS TRANSPLANTS (CONGRESSMAN GORE)
November 9, 1983	HEARINGS ON BUYING AND SELLING OF ORGANS FOR TRANSPLANTATION (CONGRESSMAN GORE)
November 14, 1983	HEARINGS ON PAYMENT OF OUTPATIENT IMMUNOSUPPRESSIVE DRUGS (CONGRESSMAN WAXMAN)
January 23-24, 1984	FIRST MEETING OF THE AMERICAN COUNCIL ON TRANSPLANTATION
February 9, 1984	HEARINGS ON HR-4080

of liver transplants, and the shortage of these vital organs. Congressman Gore (cited in Iglehart, 1983a) opened the hearings with the following comment:

> Each of us has been moved by the stories of families seeking life-saving organs for their critically ill loved ones... I am sure that many of you have wondered, as I have, why there is not some system to help meet those compelling needs in a more rational way...It was for this very reason, especially after I was personally contacted to assist in such a search, that I directed the subcommittee staff to conduct the investigation which has brought us here today.

During the course of these hearings, Iglehart (1983a) notes that:

> The interest of the legislators who were party to the inquiry...was provoked by recent media attention to the plight of families with children who have an incurable liver disease, biliary atresia, and need liver transplantation. As they addressed the issues, the legislators found themselves confronted by an array of social, economic, political, and ethical questions, such as. "Who shall live?" "Who shall pay?" and "Who shall decide?"

These apparently "new" problems are the very same problems that led to the National Heart Transplantation Study. The Gore hearings, however, did much to generate interest in improving the organ procurement system.

The Surgeon General, C. Everett Koop, has also become involved in the controversy. He convened a special workshop on June 7-9, 1983 at Project HOPE in Millwood, Virginia to also address organ procurement issues. Some 40 people participated in the conference. In his keynote address the Surgeon General (cited in Iglehart, 1983c) said:

> ...whatever success has been achieved so far in organ procurement is only a modest beginning, a small toe-hold on what may be difficult a climb as the north face of

> Everest...I think it's important for us to accept the current system of organ procurement as voluntary, decentralized and imperfect, but nevertheless open to improvement. And, having accepted it, relay that information to the public in the most reassuring way possible.

On June 20-23, 1983 another group met to discuss transplantation--this time the issue under consideration was the current status of liver transplantation. The Office of Medical Applications of Research (OMAR) held a Consensus Development Conference to discuss the medical and scientific aspects of liver transplantation. At the outset of the conference, the Panel members were instructed to limit their attention to five "key" questions. They were:

- Are there groups of patients for whom transplantation of the liver should be considered appropriate therapy?
- What is the outcome (current survival rates, complications) in different groups?
- In a potential candidate for transplantation, what are the principles guiding selection of the appropriate time for surgery?
- What are the skills, resources, and institutional support needed for liver transplantation?
- What are the directions for future research?

The panel was instructed specifically to ignore the social, economic, and ethical issues that may be associated with liver transplantation. The report of Dr. Roger W. Evans (1983), however, did comment upon the importance of the very issues that were being ignored.

At the conclusion of the Consensus Development Conference, the consensus statement declared that (Consensus Conference, 1983):

> After extensive review and consideration of all available data, this panel concludes that liver transplantation is a therapeutic modality for end-stage liver disease that deserves broader application. However, for liver transplantation to gain its full therapeutic potential, the indications for and results of the procedure must be the object of comprehensive coordinated, and ongoing evaluation in the years ahead. This can best be achieved by expansion of this technology to a limited number of centers where performance of liver transplantation can be carried out under optimal conditions.

Such a statement is particularly problematic for policymakers in both the public and private sectors because it signals the fact that liver transplantation has now entered the realm of therapy, and should be considered eligible for reimbursement. Private and public insurers have largely balked at the recommendations. Only a select few have actually decided to cover liver transplantation. Medicare still does not pay for liver transplants and only a few selected state Medicaid programs have opted for coverage.

Many third party payers, including HCFA, have further delayed making a coverage decision. HCFA is in the process of reviewing a report prepared by the Office of Health Technology Assesssment (OHTA). That report has been reviewed by the Department of Health and Human Services. The report was prepared by Drs. Enrique Carter and Harold Marguiles (now retired). However, this report, like that issued by OMAR, provides a review of the medical and scientific aspects of liver transplantation with minimal commentary on the social, economic, ethical, and legal implications of the procedure.

A decision has yet to be made concerning Medicare reimbursement for liver transplantation, although in testimony before a House Ways and Means health subcommittee hearing on February 9, 1984, Department

of Health and Human Services Assistant Secretary for Health, Dr. Edward Brandt, declared that liver transplantation was non-experimental for children with "...biliary atresia and other rare congenital abnormalities," but noted that "...additional clinical trials should be conducted for other conditions leading to end-stage liver disease." Brandt said that the Department of Defense' health benefits program--CHAMPUS--will issue regulations allowing reimbursement of retired military personnel and their families for liver transplants. Blue Cross and Blue Shield of Massachusetts recently announced that it will include liver transplantation as part of its standard benefit package. While many view a favorable decision on behalf of Medicare to be essential, such a decision would not be of great help to most people in need of liver transplants since the majority, given current patient selection criteria, would not meet the program eligibility requirements. In transmitting the Office of Health Technology Assessment report on liver transplantation to the Health Care Financing Administration, Assistant Secretary Brandt cautioned Dr. Carolyne Davis "...to review the report carefully and to proceed cautiously in making a final determination about coverage of liver transplantation." He expressed concern that, in his estimation, there remain "...serious questions...regarding the selection of recipients for liver transplants."

The recent attention focused on liver transplantation has clearly complicated the issues peculiar to heart transplantation. Heart transplantation is clearly a superior treatment modality when compared with liver transplantation. Thus, it becomes difficult to continue to declare heart transplantation experimental or investigative if liver

transplantation is therapeutic. A comparative assessment of patient survival rates is provided in Table 1-8. As shown here, based on an analysis of survival of liver transplant recipients prepared by Scharschmidt (1983) for the OMAR consensus conference, and the results reported for heart transplantation by the Stanford team, the differences are substantial. Even the better results of the liver program at Pittsburgh, using cyclosporine, still lag behind those of heart transplantation. It is clear a dilemma, if not an impasse, has been created.

On September 21-22, 1983 the Surgeon General convened a second, more wide-ranging workshop on a variety of issues associated with organ transplantation, including the ethical issues. This meeting culminated in the formation of the American Council on Transplantation (ACT) which held its first meeting on January 23-24, 1984. ACT has been characterized as a private sector initiative with several major objectives, including:

- to motivate the public to donate organs and tissues for transplantation
- to encourage health professionals to identify donors and refer them to organ procurement programs and tissue banks
- to promote equitable access to and effective use of multiple organs and tissues
- to address the technical, ethical, and financial issues involved with organ recovery and in transplantation.

ACT has been controversial. Immediate past president of the American Society of Transplant Surgeons (ASTS)--Oscar Salvateirra, M.D.--resigned as interim Vice-President of ACT prior to its first meeting,

Table 1-8
Patient Survival for Recipients of
Liver and Heart Transplants

TRANSPLANT PROCEDURE	SURVIVAL YEAR 1-YEAR	2-YEAR	3-YEAR	4-YEAR	5-YEAR
HEART TRANSPLANT PATIENT					
Stanford (1974-1981)[1]	63%	55%	51%	44%	39%
Stanford (After 3 mos)[1]	78%	66%	58%	48%	42%
LIVER TRANSPLANT PATIENT					
With Neoplastic Disease[2]	26%	--	12%	--	--
Without Neoplastic Disease[2]	39%	--	30%	--	
Pittsburgh Only[3]	70%	--	60%	--	--

[1]Pennock et al., 1982

[2]Scharschmidt, 1983

[3]Starzl et al., 1983

charging that it was "highly political." Iglehart (1984:867) has described the short, yet stormy history of the ACT as follows:

> Although ACT has held only a few meetings since its creation, it is already embroiled in controversy. The transplantation community is divided over whether ACT has the potential to become an effective coordinating mechanism for the disparate organizations involved in this medical discipline. More than one transplant surgeon has questioned the motives of the administration in pressing the interests of a private organization so hard, wondering whether ACT is serving mostly as a stalking-horse to head off legislation.

The President of ACT, Dr. Gary Friedlaender, has strongly denied these criticisms. Moreover, many of the groups represented within ACT are at odds with one another over a variety of issues. Over time, perhaps, these differences can be resolved and the organization will take on the functions that it envisions for itself. At least Assistant Secretary for Health of the Department of Health and Human Services, Dr. Edward N. Brandt, Jr., foresees a sorting-out of differences:

> ...we should wait until it (ACT) has had a fair chance to deal with coordinating the activities of the various organizations. I just do not believe that direct government involvement in the procurement of organs will necessarily improve the system any further (cited in Iglehart, 1984:867).

Between October 17, 1983 and November 14, 1983 hearings were held on the proposed National Transplantation Act. Separate hearings were held on the transplantation of foreign nationals, the buying and selling of organs for transplantation, and the payment of outpatient immunosuppressive drugs for transplant recipients. Finally, a new round of hearings began on February 9, 1984 before the House Ways and Means Committee.

The National Heart Transplantation Study has served as a national as well as international resource upon which government officials, policymakers, consumers, medical professionals, and other interested scientists have been able to draw for information and insight. Dr. Evans has participated in two Congressional hearings, and was asked to participate in others but has been unable to do so. He has also attended both workshops held by the Surgeon General, and served as a Forum member at the NIH Consensus Conference on Liver Transplantation. As an international resource, the National Heart Transplantation Study has proven to be an exceedingly important study. This is a great tribute not only to those who have labored on the study, both in Seattle and elsewhere, but to the project sponsor--the Health Care Financing Administration--which persevered through many times of crisis to see the study through to its completion.

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APPENDIX 1-A

JANUARY 21, 1980 MEMORANDUM FROM DR. PETER L. FROMMER

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

TO : Director, Coverage Assessment Staff
National Center for Health Care Technology

DATE: January 21, 1980

Through: Director, National Center for Health Care Technology

FROM : Deputy Director, NHLBI

SUBJECT: Medicare Coverage of Heart Transplants

1. In view of the recent Medicare inquiry about possible reimbursement for cardiac transplantation, you have solicited NHLBI's judgment about the safety and efficacy of that procedure and whether it should no longer be considered experimental.

The Preparation of this Response and the Comments of Consultants

2. In preparing this response, NHLBI first prepared a draft document (Attachment 1) and distributed it for comment to 18 consultants (Attachment 2) approximately evenly divided among the areas of cardiology, cardiovascular surgery, and transplantation surgery. Comments were received by telephone from 17 consultants, and to date written responses have been received from 15.

3. The recommendations of the draft document were:

"It is recommended that:

1. Cardiac transplantation be accepted for reimbursement at those centers which have experience, which utilize the Stanford criteria for patient selection and the essential features of the Stanford procedure for patient management.

2. Further centers be accepted for reimbursement only if they:

   a. demonstrate the expertise and resources necessary for the procedure,

   b. fully adhere to the protocol for patient selection and at least the essential criteria for patient evaluative and therapeutic procedures upon which these recommendations are made,

   c. are a part of regionalized plan - i.e., represent a center for cardiac transplantation for a region of reasonable dimensions in terms of needs, medical manpower, and logistics, and

   d. maintain and forward records which characterize the patients selected, the procedures used, and the short and long term outcomes.

3. There be alertness for several "dangers":

   a. The forces for the proliferation of centers which do not fully meet the criteria above.

   b. Unwarranted changing - particularly loosening - the criteria for patient acceptance.

   c. Unwarranged rigidity in adhering to current protocols of patient selection and patient management at times in the future when new evidence is developed germane to the topic of safety, efficacy and reasonableness."

4. These recommendations were fully supported by 15 of the 17 respondents. Two of the 15 pointed out that the first two recommendations could be interpreted to suggest that some of those institutions already involved in clinical transplantation might be "grandfathered" without having to meet the criteria for others. The recommendations have been revised (a) to clarify this, (b) to take into account the fact that Medicare reimburses for medical care of individuals rather than the medical care programs of institutions, and (c) that there was unanimous support that Stanford and the transplantations at Stanford were fulfilling requisite criteria. The 16th respondent recommended controlled expansion for the support of cardiac transplantation at several additional centers beyond Stanford, but was not certain whether Medicare reimbursement was the appropriate control mechanism. The 17th respondent felt that cardiac transplantation should be reimbursed by Medicare, but that rather than singling this procedure out for special guidelines, institutional review boards and careful and continuing scrutiny of the profession should delineate its utilization; the proposed procedure would be too constricting and stultifying and interfere with appropriate utilization of cardiac transplantation in other circumstances where it has already been used with some success in small numbers of patients.

5. Most respondents strongly emphasized the importance of one or more of the points under recommendation 3. There was broad support for careful control of expansion of cardiac transplantation, several consultants giving this utmost priority. A number of consultants emphasized both the desirability and the difficulty of such restrictive expansion. Several consultants wanted to reemphasize item 3, c, the hazard of unwarranted rigidity in adhering to current protocols after new data are developed. The minor rewording of recommendation 3 reflects these views, which the Institute shares.

6. Several comments were also received on the body of the report, and some of these have resulted in modifications therein. Other changes are also present, including more complete information on costs and the addition of the section Conclusions.

A Discussion of the Issues

7. In addition to the question of safety and efficacy of cardiac transplantation, there are several additional questions in the broad categories of "Is it reasonable?" and "Are there other factors to be considered?", which are germane to a coverage issue of this type. Specifically:

a. Is the cost comparable to or less than the cost of alternate procedures of comparable net benefit - or is the extra cost justified on the basis of commensurate extra benefit?

b. Are the net benefits worth the cost?

c. Are there special characteristics of the procedure which should enter into the consideration - e.g., ethical issues, societal and economic impact, the setting of precedent, etc.?

d. To what extent are the results to date generalizable - e.g., Can the results obtained in any setting be expected to be comparable to those upon which current judgment is based? Can the results obtained from this group of patients by these techniques be extrapolated to somewhat similar patients or somewhat similar techniques?

8. Each question will be addressed successively.

9. At the outset it must be emphasized that in considering the results of cardiac transplantation, one cannot simply consider the surgical procedure; one must consider the full therapeutic and evaluative regimen, including the roles of medical cardiology, immunology and infectious disease, as well as cardiac surgery.

Is cardiac transplantation effective and safe?

10. Candidates who meet the Stanford criteria* and are accepted for transplantation have sufficiently advanced and progressive heart disease that while awaiting transplantation about one-fourth of the candidates die. Of those who undergo transplantation and the extensive immunosuppressive therapy, over 65% have a one-year survival and actuarial curves indicate a 50% five-year survival. The one-year survival and the first half of this actuarial curve have improved slightly in recent years, so it is likely that the total actuarial curve will at least be maintained or improved.

*In summary, the criteria are persons under the age of 50 who, except for end-stage cardiac disease (cardiac functional class IV or a poor 6-month prognosis for survival), are vigorous and healthy and have a stable psychological and social situation. (See Attachment 3.) The judgments about cardiac status and prognosis are quite narrow.

11. Thus, in the patients accepted by the Stanford group and with the surgical, immunosuppressive, diagnostic and evaluative methods of the Stanford group, the procedure is unequivocally effective and safe.

Should the procedure no longer be considered experimental?

12. For patients meeting the Stanford criteria, the Stanford procedures in the hands of the Stanford group yield reproducibly safe and effective results. Thus, the basic procedure in this patient group is no longer "experimental".

13. The Stanford group, as others, is continuing research and refinements on the techniques to further improve their success. Thus, a minor fraction of their effort and cost is indeed experimental, but the major fraction of the effort and cost - the diagnostic and surgical procedures and the majority of the immunosuppression and evaluative procedures - are standardized and have clearly predictable and quite acceptable results, and are thus beyond the experimental stage.

Is the cost comparable to or less than the cost of alternate procedures of comparable net benefit - or is the extra cost justified on the basis of commensurate extra benefit?

14. There are at this time no alternate procedures approaching comparable net benefit - i.e., in the patients meeting the Stanford criteria, there are no means of achieving 65% one-year and 50% five-year survival; the alternative of no transplantation yields less than a 10% one-year survival.

Are the net benefits worth the cost?

15. This is a question which must be answered by society in general, not by medicine specifically. However, some facts can be used to put this in perspective.

16. The cost of the procedure at Stanford - the surgery, immunosuppression, and the management of rejection - has typically run on the order of $70,000* in the first year (predominantly in the first 2 or 3 months). Continued costs vary even more widely, but have averaged on the order of $10,000 per annum when rehospitalization for late complications and for regular evaluative studies are added to outpatient costs. Estimating an average survival and increase of life by four years, this would come to something on the order of $30,000 per year of life saved, and for most patients, a major fraction of this time is good quality life.

*All costs in this and the next section are estimates of hospital charges and are not inclusive of professional services. These cardiac transplantation costs should neither be automatically considered as reasonable and necessary medical care costs, nor should they be considered the upper limit of costs; they are presented as an order of magnitude.

17. For comparative purposes, in patients with, say, carcinoma of the pancreas, the surgical procedure and recovery period may easily incur costs of $10,000 or more, but are unlikely to increase life by more than 6 to 12 months. For chronic hemodialysis with advanced renal disease, the annual cost is on the order of $30,000 (including professional fees). Renal transplantation, which on the whole is accompanied by success in a comparable or slightly lower fraction of patients than the current cardiac transplantation series, costs on the order of $30,000 and also incurs continued annual costs. For advanced heart disease with repeated hospitalizations, the care costs may be in the tens of thousands of dollars without ever returning the patient to an active life.

18. Society has the responsibility for the judgment whether the benefit is worth the cost, but for other procedures of comparable cost per year of improved life expectancy, society has accepted cost reimbursement.

Are there special characteristics of the procedure which should enter into the consideration - e.g., ethical issues, societal and economic impact, the setting of precedent, etc.?

19. Ethical issues and societal impact have been the topic of extensive discussion and reports. None of these stand in the way of considering this an accepted form of therapy.

20. As the procedure becomes more widely accepted, difficult choices in the allocation of scarce resources will be increasingly frequent and increasingly difficult. The most seriously limiting factor currently is the availability of donor hearts, but facilities for doing the procedure and other resoruces may become factors as well, particularly were the criteria for patient acceptance to broaden substantially.* The difficulty of making equitable allocation of scarce resources must be considered by those responsible for the procedure and their advisors who may assist in such allocations, but the existence of such difficulties should not influence the question of reimbursement. (To argue that it is unethical to use a resource which is so scarce that its availability is limited to only a fraction of those who could benefit from it, is analagous to arguing that if not everyone can fit into the only lifeboat from a sinking ship, it is unethical for anyone to get in.)

*From the availability of cadaver donor kidneys, it is estimated that on the order of 1,000 donor hearts might be available annually. This rough calculation is based upon the fact that approximately 8,000 cadaver donor kidneys are obtained annually, two from each cadaver, but of the 4,000 cadavers, it is certain that less than half would have hearts suitable for cardiac transplantation, and of this half a further 50% would probably be lost because of unwillingness of the family to donate a heart as readily as kidneys. This is a rough estimate of the availability of donor hearts. It ignores such factors as the possibility that there may be stronger forces for obtaining donors when the potential recipients are dying of heart disease rather than living with the inconvenience of chronic hemodialysis. Nevertheless it probably provides a reasonable order of magnitude.

21. It is somewhat hazardous to estimate the economic impact of procedures which may be widely needed and for which the needy have a strong emotional appeal. Nevertheless, the intrinsically limited availability of donor hearts should constrain the economic impact of cardiac transplantation well within the acceptable range, even if the criteria for effectiveness were much greater. It is worth noting that for cardiac replacement with a fabricated prosthetic device rather than by transplantation, this limitation would no longer exist. This emphasizes the importance of developing and utilizing objective criteria for the indications for cardiac transplantation and broadening them only when warranted by evidence.

22. The consideration of potential economic impact upon society does illustrate an important concept: The benefit may be worth the cost when compared to other procedures which are accepted by society. However, if an expensive procedure is developed which would be done on a very wide scale, society may have to reconsider whether the aggregate cost is acceptable. This may require the redefinition of what is an acceptable cost-benefit ratio. However, this is a generic issue involving society's resonsibilities in catastrophic illness and for catastrophic insurance. A discussion of what benefit at what cost would have to look at a whole range of medical and perhaps social topics, rather than singling out an individual one.

23. Reimbursement for cardiac transplantation would be precedent-setting only in that it addresses a topic of extraordinary emotional impact and societal interest.

24. Reimbursement for cardiac transplantation may require the establishment of procedures for sharply defining patient groups and for qualifying institutions (as discussed below) which may require the setting of precedent.

To what extent are the results to date generalizable - e.g., can the results obtained in any setting be expected to be comparable to those upon which current judgment is based? Can the results obtained from this group of patients by these techniques be extrapolated to somewhat similar patients or somewhat similar techniques?

25. The conclusions about effectiveness and utility have certain important limitations upon their generalizability.

26. Now, and in the next several years, it is unlikely that the procedure can be carried out in more than a limited number of places with comparable results. This is true because of the limited availability of donor hearts and the need for extensive experience and facilities. Currently there are approximately 160 institutions involved in renal transplantation. With the favorable Stanford experience and the resurgence of interest in cardiac transplantation, several additional groups have become involved in clinical cardiac transplantation, but there are still only about six

such groups in the United States, and Stanford still does about half of the transplants, two other groups do substantial numbers, and the balance have done very few. Given the limitation of donor hearts and the need to concentrate experience, it would seem unlikely and unreasonable to anticipate more than 10 or 20 groups doing cardiac transplantation in the U.S. according to the recommendations of this memorandum, for at least the next five years.

27. The Stanford experience and the Stanford criteria and procedures have been used as a basis for discussion and recommendation because these are ones that have been developed and published and stood the test of time.

28. While the survival results attained in this group of patients can probably be extrapolated to the results of somewhat similar patients, whether the procedure is reasonable in similar patients of lesser degree of illness is yet to be documented. Cardiac disease comes in all grades of severity, and the Stanford group has chosen the sickest of the sick. Currently about 80% of patients referred are rejected "long-distance", and half of the balance are rejected after they are seen at Stanford. Even among the ones they reject after examination, a substantial fraction die within a year. However, before less severely ill patients are accepted as appropriate for this procedure, detailed characteristics of such patient groups will have to be developed and it will have to be shown that their prognosis is indeed substantially less favorable with other forms of therapy than with what transplantation has to offer.

29. Deciding whether a "somewhat similar technique" can be expected to yield similar and acceptable results, and should thus be accepted for reimbursement, will involve some expert judgment calls, which will require the advice of expert consultants working as a committee. For making such a decision, it will be useful to think of the Stanford protocol for evaluative and therapeutic procedures as having some components which would be judged (a) essential and unchangeable, others (b) essential but for which alternate procedures might be acceptable as equally effective, others (c) sound and reasonable medical care but not essential, possibly others (d) which are neither necessary for sound medical care nor for research, and others (e) primarily research. When a "somewhat similar technique" is considered for reimbursement and is justified significantly upon the Stanford experience, a judgment must be made that components (a) and (b) above are fulfilled and that there are no additional (i.e., "non-Stanford") procedures which would interfere with the expected outcome. Nothing should stand in the way of considering completely dissimilar techniques and protocols for possible reimbursement, but the extent they could be justified by the Stanford experience would have to be quite limited; indeed, they would have to be considered primarily on the basis of their own "track records".

30. For purposes of reimbursement, the costs of procedures in categories a, b and c of the above paragraph would seem appropriate.

Conclusions

1. In assessing and commenting upon results of cardiac transplantation, consideration must be given not only to the surgical procedure, but to the full therapeutic and evaluative regimen which begins with the definitive assessment of potential candidates and continues through their acute and subsequent lifelong management.

2. For patients meeting specific criteria and managed according to specific therapeutic and evaluative protocols, the Stanford group has achieved reproducible results in terms of a major increment in life expectancy and an improvement in the quality of life at a cost per year of life saved in the same range as a significant number of other widely practiced therapies. The Stanford experience is thus considered safe, effective, and reasonable medical practice.

3. While comparable results can reasonably be expected at a limited number of other institutions or perhaps by different therapeutic and evaluative protocols or in patients meeting different criteria, a generalized or unqualified statement about the safety, effectiveness, and reasonableness of cardiac transplantation cannot be made.

4. The conclusions about safety, efficacy and reasonableness are based strictly upon, and therefore are at this time limited to, results in patients meeting certain specific criteria, who are managed and evaluated according to certain specific protocols, by skilled and specially experienced physicians and surgeons, with special resources. Recommendations about Medicare coverage must be comparably qualified and limited.

5. Logistical considerations and efficiencies, and the need to concentrate experience are important factors which dictate the importance of restricting cardiac transplantation reimbursement to specific centers.

6. It is plausible that certain variations upon the protocols cited may be expected to yield comparably acceptable results, but in the absence of direct clinical evidence to this effect, such judgments can only be made by those expert in the relevant fields.

7. The experience cited represents medical practice which is no longer "experimental", but facets of clinical cardiac transplantation and medical science relevant thereto continue as topics of research. It is plausible that evidence may be presented of other indications and other protocols of comparable or greater benefit.

8. Central maintenance and analysis of summary data about patients selected, procedures used and short and long-term outcomes are desirable for continued assessment of cardiac transplantation, particularly as experience becomes available from multiple institutions and potentially according to different protocols.

Recommendations

1. Cardiac transplantation should be accepted for Medicare reimbursement only at those centers which:

   a. demonstrate the expertise, resources, logistical plans and anticipated continuing concentration of experience necessary for high quality results,

   and for patients:

   b. who fulfill the "Stanford criteria" for patient selection, and

   c. whose therapeutic and evaluative procedures include at least the minimum components of the "Stanford protocol" or acceptable equivalents.

2. Cardiac transplantation at Stanford fulfills the above criteria and should be accepted for Medicare reimbursement.

3. Judgments whether other institutions, other patient criteria, or other evaluative and therapeutic protocols fulfill the above criteria should be made by a committee or committees made up predominantly of experts in the areas of medical cardiology, cardiac surgery, and transplantation.

4. Consideration should be given to the establishment of a central registry of cardiac transplantation, to which submission of summary data would be a requisite for reimbursement.

5. There must be alertness for several dangers which must be forcefully resisted or carefully avoided:

   a. The forces for the proliferation and acceptance of centers which do not fully meet the criteria above.

   b. Unwarranted changing - particularly loosening - the criteria for patient acceptance.

   c. Unwarranted rigidity in adhering to current protocols of patient selection and patient management at times in the future when new evidence is developed germane to the topic of safety, efficacy and reasonableness.

Peter L. Frommer

Peter L. Frommer, M.D.

cc: Dr. Fredrickson
Dr. Levy

Attachment 1

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

TO : Director, Coverage Assessment Staff
National Center for Health Care Technology

DATE: December 7, 1979

Through: Director, National Center for Health Care Technology

FROM : Deputy Director, NHLBI

DRAFT

SUBJECT: Medicare Coverage of Heart Transplants

1. In view of the recent Medicare inquiry about possible reimbursement for cardiac transplantation, you have solicited NHLBI's judgment about the safety and efficacy of that procedure and whether it should no longer be considered experimental.

2. There are several additional questions - in the broad categories of "Is it reasonable?" and "Are there other factors to be considered?" - which I think are germane to a coverage issue of this type, and I will try to address them as well. Specifically:

a. Is the cost comparable to or less than the cost of alternate procedures of comparable net benefit - or is the extra cost justified on the basis of commensurate extra benefit?

b. Are the net benefits worth the cost?

c. Are there special characteristics of the procedure which should enter into the consideration - e.g., ethical issues, societal and economic impact, the setting of precedent, etc.?

d. To what extent are the results to date generalizable - e.g., Can the results obtained in any setting be expected to be comparable to those upon which current judgment is based? Can the results obtained from this group of patients by these techniques be extrapolated to somewhat similar patients and somewhat similar techniques?

3. Let us go through these questions one by one.

Is cardiac transplantation effective and safe?

4. Candidates who meet the Stanford criteria and are accepted for transplantation have sufficiently advanced and progressive heart disease that while awaiting transplantation about one-fourth of the candidates die. Of those who undergo transplantation and the extensive immunosuppressive therapy, over 65% have a one-year survival and actuarial curves indicate a 50% five-year survival. The one-year survival and the first half of this actuarial curve have improved slightly in recent years, so it is likely that the total actuarial curve will at least be maintained or improved.

DRAFT

5. Thus, in the patients accepted by the Stanford group and with the surgical, immunosuppressive, diagnostic and evaluative methods of the Stanford group, the procedure is unequivocally effective and safe.

Should the procedure no longer be considered experimental?

6. For patients meeting the Stanford criteria,* the Stanford procedures in the hands of the Stanford group yield reproducibly safe and effective results. Thus, the basic procedure in this patient group is no longer "experimental".

7. The Stanford group, as others, is continuing research and refinements on the techniques to further improve their success. Thus, a minor fraction of their effort and cost is indeed experimental, but the major fraction of the effort and cost - the diagnostic and surgical procedures and the majority of the immunosuppression and evaluative procedures - are standardized and have clearly predictable and quite acceptable results, and are thus beyond the experimental stage.

Is the cost comparable to or less than cost of alternate procedures of comparable net benefit - or is the extra cost justified on the basis of commensurate extra benefit?

8. There are at this time no alternate procedures approaching comparable net benefit - i.e., in the patients meeting the Stanford criteria, there are no means of achieving 65% one-year and 50% five-year survival; the alternative of no transplantation yields less than a 10% one-year survival.

Are the net benefits worth the cost?

9. This is a question which must be answered by society in general, not by medicine specifically. However, some facts can be used to put this in perspective.

10. The cost of the procedure - the surgery, immunosuppression, and the management of rejection typically run on the order of $60,000** in the first year (predominantly in the first 2 or 3 months). Continued costs for the patients are on the order of $2,500 per annum. Estimating a median survival and increase of life by four years, this would come to something on the order of $17,000 per year of life saved, and for most patients, a major fraction of this time is good quality life.

*In summary, the criteria are persons under the age of 50 who, except for end stage cardiac disease (cardiac functional class IV or a poor 6-month prognosis for survival), are vigorous and healthy and have a stable psychological and social situation. The judgments about cardiac status and prognosis are quite narrow.

**All costs in this section are estimates of hospital charges and are not inclusive of professional services.

DRAFT

11. For comparative purposes, in patients with, say, carcinoma of the pancreas, the surgical procedure and recovery period may easily incur costs of $10,000 or more, but are unlikely to increase life by more than 6 to 12 months. For chronic hemodialysis of terminal renal disease, the annual cost is on the order of $30,000 (including professional fees). Renal transplantation, which on the whole is accompanied by success in a slightly lower fraction of patients than the current cardiac transplantation series, costs on the order of $30,000.

12. Society has the responsibility for the judgment whether the benefit is worth the cost, but for other procedures of comparable or higher cost per years of improved life expectancy, society has accepted cost reimbursement.

Are there special characteristics of the procedure which should enter into the consideration - e.g., ethical issues, societal and economic impact, the setting of precedent, etc.?

13. Ethical issues and societal impact have been the topic of extensive discussion and reports. None of these stand in the way of considering this an accepted form of therapy.

14. As the procedure becomes more widely accepted, difficult choices in the allocation of scarce resources will be increasingly frequent and increasingly difficult. The most seriously limiting factor currently is the availability of donor hearts, but facilities for doing the procedure and other resoruces may become factors as well, particularly were the criteria for patient acceptance to change.* The difficulty of making equitable allocation of scarce resources must be considered by those responsible for the procedure and their advisors who may assist in such allocations, but the existence of such difficulties should not influence the question of reimbursement. (To argue that it is unethical to use a resource which is so scarce that its availability is limited to only a fraction of those who could benefit from it, is analagous to arguing that if not everyone can fit into the only lifeboat from a sinking ship, it is unethical for anyone to get in.)

*On the availability of cadaver donor kidneys, it is estimated that on the order of 1,000 donor hearts might be available annually. This rough calculation is based upon the fact that approximately 8,000 cadaver donor kidneys are obtained annually, two from each cadaver, but of the 4,000 cadavers, it is certain that less than half would have hearts suitable for cardiac transplantation, and of this half a further 50% would probably be lost because of unwillingness of the family to donate a heart as readily as kidneys. This is a rough estimate of the availability of donor hearts, but it provides a reasonable order of magnitude.

DRAFT

15. The economic impact upon society warrants consideration only because it illustrates an important concept: The benefit may be worth the cost when compared to other procedures which are accepted by society. However, if an expensive procedure is developed which would be done on a very wide scale, society may have to reconsider whether the aggregate cost is acceptable. This may require the redefinition of what is an acceptable cost-benefit ratio. However, this is a generic issue involving society's resonsibilities and catastrophic illness and catastrophic insurance. A discussion of what benefit at what cost would have to look at a whole range of medical and perhaps social topics rather than singling out an individual one.

16. Reimbursement for cardiac transplantation would be precedent-setting only in that it addresses a topic of extraordinary emotional impact and societal interest.

17. Reimbursement for cardiac transplantation may require the establishment of procedures for sharply defining patient groups and for qualifying institutions (as discussed below) which may require the setting of precedent.

To what extent are the results to date generalizable - e.g., can the results obtained in any setting be expected to be comparable to those upon which current judgment is based? Can the results obtained from this group of patients by these techniques be extrapolated to somewhat similar patients and somewhat similar techniques?

18. The conclusions about effectiveness and utility have certain important limitations upon their generalizability.

19. Now, and in the next several years, it is unlikely that the procedure can be carried out in more than a limited number of places with comparable results. This is true because of the limited availability of donor hearts and the need for extensive experience and facilities. Currently there are approximately 160 institutions involved in renal transplantation. With the favorable Stanford experience and the resurgence of interest in cardiac transplantation, several additional groups have become involved in clinical cardiac transplantation, but there are still only about six such groups in the United States, and Stanford still does about half of the transplants, two other groups do substantial numbers, and the balance have done very few. Given the limitation of donor hearts and the need to concentrate experience, it would seem unlikely and unreasonable to anticipate more than 10 or 20 groups doing cardiac transplantation in the U.S. according to the recommendations of this memorandum for at least the next five years.

20. The Stanford experience and the Stanford criteria and procedures have been used as a basis for discussion and recommendation because these are ones that have been developed and published and stood the test of time.

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21. While the survival results attained in this group of patients can probably be extrapolated to the results of somewhat similar patients, whether the procedure is reasonable in similar patients of lesser degree of illness is yet to be documented. Cardiac disease comes in all grades of severity, and the Stanford group has chosen the sickest of the sick. Currently about 80% of patients referred are rejected "long-distance", and half of the balance are rejected after they are seen at Stanford. Even among the ones they reject after examination, a substantial fraction die within a year. However, before less severely ill patients are accepted as appropriate for this procedure, detailed characteristics of such patient groups will have to be developed and it will have to be shown that their prognosis is indeed substantially less favorable with other forms of therapy than what transplantation has to offer.

22. The Stanford protocol for evaluative and therapeutic procedures should be thought of as constituting a major patient care component and a minor research component. The patient care component should in turn be considered as constituting a component of essential procedures thought necessary to achieve the current results, and a second component representing the range of acceptable medical care (but possibly not its upper limit). For eventual coverage decisions, the Stanford procedures would then have to be broken into these three categories: "essential" and "acceptable" (which would be covered), and "research" (which would be outside coverage).

23. Extrapolation of present results and conclusions to those that might be obtained using "somewhat similar techniques" is difficult. It is in part for this reason that the present procedures need to be broken down into their "essential", "acceptable", and "research" components. The "essential" must be fulfilled. It is plausible that there may be "equivalents" within the range of "acceptable" which are neither research nor a part of the current Stanford procedure, but simply an alternate to how transplantation patients (such as renal) and cardiac patients may be handled. Other variants, however, must be considered "research" and outside the realm of coverage. Developing these criteria and subgroups requires an expert consultation committee.

Recommendations

It is recommended that:

1. Cardiac transplantation be accepted for reimbursement at those centers which have experience, which utilize the Stanford criteria for patient selection and the essential features of the Stanford procedure for patient management.

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2. Further centers be accepted for reimbursement only if they:

   a. demonstrate the expertise and resources necessary for the procedure,

   b. fully adhere to the protocol for patient selection and at least the essential criteria for patient evaluative and therapeutic procedures upon which these recommendations are made,

   c. are a part of regionalized plan - i.e., represent a center for cardiac transplantation for a region of reasonable dimensions in terms of needs, medical manpower, and logistics, and

   d. maintain and forward records which characterize the patients selected, the procedures used, and the short and long term outcomes.

3. There be alertness for several "dangers":

   a. The forces for the proliferation of centers which do not fully meet the criteria above.

   b. Unwarranted changing - particularly loosening - the criteria for patient acceptance.

   c. Unwarranted rigidity in adhering to current protocols of patient selection and patient management at times in the future when new evidence is developed germane to the topic of safety, efficacy and reasonableness.

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Attachment 3

January 1980

"STANFORD CRITERIA" FOR SELECTION OF CARDIAC TRANSPLANT RECIPIENTS

Medical Considerations:

1. The patient must have a poor prognosis for six months survival. This prognosis may be the result of either a poor cardiac functional status or an uncontrollable recurrent ventricular arrhythmia.

2. All medical and surgical therapies must have been considered and/or tried which might be expected to yield an immediate and one-year survival similar to that of cardiac transplantation.

3. Except for end-stage cardiac disease, the patient must be a vigorous and healthy individual who would benefit from the transplant procedure.

   Criteria include:

   a. Under 50 years.

   b. No other active systemic disease: e.g., insulin-requiring diabetes mellitus, symptomatic peripheral or cerebrovascular disease, peptic ulcer disease, metabolic abnormalities such as amyloidosis, malignancy.

   c. No obesity which would create a problem in finding a suitable donor.

   d. The following end organ complications of the cardiac disease exclude the patient from consideration:

      1. unresolved pulmonary infiltrate (other than pulmonary edema)

      2. recent or unresolved pulmonary infarction

      3. severe hepatic or renal abnormalities

      4. severe pulmonary hypertension reflected by a pulmonary artery systolic pressure over 65-70 mm Hg when pulmonary artery wedge pressure is 20-30 mm; or a pulmonary vascular resistance of 5-6 Wood units.

Psychological Considerations:

The cardiac transplant patient tends to respond to the stress of transplantation in a manner similar to his response to the stress of his cardiac disease. Current attitudes and compliance with medical directions must be carefully assessed to determine whether the patient can faithfully follow a complex immunosuppressive drug, exercise and dietary regimen for the rest of his life.

1. The patient should be optimistic and have a strong desire to live.

2. The patient must have demonstrated emotional stability and a realistic attitude to his current illness and to prior severe stresses.

3. A history of alcoholism, job instability, antisocial behavior, or significant psychiatric illness are contraindications.

Social Considerations:

At the present time the arduous post-transplant course requires strong emotional family support to provide optimal chance for success and rehabilitation.

1 The patient must have a strong desire to live and have a stable, rewarding family and/or vocational environment to return to post-transplantation.

2. The patient should have spouse, family, or other companions who are able and willing to make a long-term commitment to providing emotional support to the patient both pre- and post-transplantation.

3. The patient must have a strongly supportive family or social constellation that is able and willing to tolerate the family upheaval and stresses of cardiac transplantation.

4. Financial resources must be available to the patient including:

   a. Travel to and from the transplant center accompanied by a supportive family member for final evaluation of transplantation candidacy .

   b. All pre-transplant medical care, including initial transplant candidacy evaluation and/or hospitalization, if necessary, at the transplant center.

   c. Living expenses for the patient and family while in the transplant center area before, during and after transplantation, a period which may extend six to ten months.

d. Annual travel to the transplant center indefinitely for medical follow-up or when needed for severe rejection episodes or complex infections.

Other Considerations:

The patient and family must be knowledgeable about the short and long-term risks of transplantation and the morbidity and mortality which are associated with long-term immunosuppression.

1. There must have been discussion of these guidelines with the patient and/or family, and they must have been factually informed of the transplant procedure, survival statistics, current risks, complications and financial commitment required.

2. A physician must be willing to care for this patient if he returns to the community post-transplantation. The responsible cardiologist or internist must be available, aggressive, knowledgeable (or willing to become so) in the care and complications of the immunosuppressed patient, and absolutely dedicated to keeping the patient alive long-term.

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

TO : Director, Coverage Assessment Staff
National Center for Health Care Technology

DATE: January 21, 1980

Through: Director, National Center for Health Care Technology

FROM : Deputy Director, NHLBI

SUBJECT: Heart Transplantation - Background Statement

1. Heart transplantation was first done in man in late 1967. About 100 heart transplants were done world wide the next year, 50 the following year, and then, because of failure to achieve long-term successes, the number of transplants dropped below 20 by 1970. In the ensuing years, transplantation has continued and grown slowly to approximately 50 cases per year currently.

2. Stanford University Medical Center has been in the forefront of both the fundamental scientific investigations leading to clinical cardiac transplantation and in the actual transplantation in man. Almost 200 transplants have been done, beginning at about ten a year in the late sixties and growing gradually to about 25 a year currently. Success has increased dramatically, with one-year survival growing from about 20% in 1968 to over 65% for the last several years. Five-year survival is currently in excess of 50%, and the longest survivor is now ten years post-transplantation.

3. The Stanford cardiac transplantation survival statistics are comparable to or slightly better than the survival data for most large series of renal transplants.

4. The comparison to renal transplantation, of which about 5,000 cases are done annually, is also meaningful because the major problems are basically the same. The human body has defense mechanisms which build antibodies to most foreign proteins. Thus, the transplantation of an organ from another person who is genetically not identical will result in immunological reactions which will tend to reject the transplanted organ. This propensity for rejection can generally be controlled. Initially, there is an intense effort at the suppression of the body's immune mechanisms by drugs and biologicals or radiation or other techniques. This is then followed by lifelong immune suppression by drugs. This has the side effect that the body's resistence to infection is diminished, and the transplant recipient becomes susceptible to infectious organisms commonly present in the environment to which the normal person is immune.

5. Also in common with kidney transplantation, the lack of adequate donor organs limits the number of procedures. In contrast to kidney transplants, for which the organ may be one of the two healthy kidneys of a living relative (a procedure which accounts for perhaps a quarter of kidney transplants), donor hearts, as most donor kidneys currently, must come from those who have sustained brain death and are legally dead, but still have a beating heart. Also in contrast to donor kidneys, potential donor hearts must come from young adults and are still frequently unsuitable because of the high prevalence of coronary artery disease in the population, even in persons who have no symptoms or clinical evidence of coronary heart disease.

6. In many ways, the management of the patient who has received a heart transplant is similar to that of a patient who has received a kidney transplant. An important difference is that if the transplanted kidney fails, its recipient can go on to hemodialysis, which can be repeated on a chronic basis. No such fallback mechanism now exists for the recipient of a heart transplant, and rejection of the organ poses a greater hazard.

7. The Stanford Medical Center has been universally acknowledged as the leader in the field of cardiac transplantation. Over the past decade, more than half of the cardiac transplants in the world have been done at Stanford, and the Stanford series now comprises almost 40% of the world's total.

8. Just as there are different immunosuppressive treatments for patients with kidney transplants at different centers, so there are varying techniques for immunosuppression of cardiac transplant patients. Also some institutions have used cardiac transplantation in circumstances quite different from Stanford. Nevertheless, the Stanford experience is the benchmark for comparisons. It is the most widely practiced regimen, and it is the only one which has been used in a large number of patients.

9. For the foregoing reasons, the further discussion will be focused specifically upon "the Stanford protocol". This restricted discussion is not intended to deny the potential value of variations upon the Stanford protocol or completely different protocols for patient management or patient selection.

10. Cardiac transplantation has always been reserved for patients who have far advanced heart disease with no alternate form of treatment offering significant promise. The major improvement in clinical results over the past 12 years has derived from several developments - most importantly, improved methods of immunoglogical suppression, improved methods for the recognition and early treatment of incipient rejection, more refined criteria for the selection of patients, and perhaps the therapy designed to reduce platelet aggregation and accelerated atherosclerosis.

11. Potential recipients must have end-stage heart disease with a poor prognosis for six-month survival; this judgment is based upon careful assessment of the history and response to more conventional therapies, and laboratory studies, including cardiac catheterization, coronary angiography, and other tests which may measure the performance of the heart. Patients must be under 50 years of age; older patients, who were being operated upon in earlier years, had a significantly less favorable survival. Few if any other coexisting illnesses can be present; a major reason for this is the much greater susceptibility to infection, the upset in certain endocrine balances, and the propensity for gastro-intestinal ulceration and other disorders associated with the lifelong immunosuppressive regimen which all patients must undergo. Psychosocial factors have to be assessed carefully because of the importance of withstanding the emotional as well as physical stresses of the acute and long-term management, the importance of adhering meticulously to a reasonably complex lifelong therapeutic regimen, and thus the need for family and societal support.

12. The cause of heart disease in patients receiving cardiac transplants at Stanford is coronary artery disease in about 50% of the cases; about 40% have cardiomyopathies (a disorder of the heart muscle not due to its blood supply, but typically the result of unrecognized viral infections or a variety of unknown causes); the balance have rheumatic or congenital heart disease.

13. After a potential recipient is fully evaluated and accepted as a transplant recipient, he or she must move temporarily into the Stanford area, so that he/she can be under optimal medical treatment awaiting transplantation and be ready when a donor becomes available.

14. Donors are typically in the 18 to 35-year age range and are the victims of brain death, typically following trauma or bleeding into the brain. After formal permission from family and other legal steps, a potential donor heart must be evaluated by cardiac catheterization and coronary angiography to insure that it is suitable for transplantation. To diminish the propensity for rejection, the donor and recipient must have compatible ABO blood types. More complex "tissue typing" has identified one other match which must exist. Once the donor and recipient are matched, substantial maneuvers have to be undertaken to effect transplantation within a few hours of the removal of the donor heart, even when the heart is maintained under optimal circumstances.

15. The surgical implantation procedure itself is no more complex than most cardiac surgery. With the patient on the heart-lung machine, the diseased heart is totally removed except for the parts of the right and left atria into which the venous drainage of the body and lungs drain. The donor heart is then sutured in place.

16. Following the operation, intensive immunosuppressive therapy has to be administered, and the patient becomes highly susceptible to infection. Thus, isolation techniques are utilized as if the patient had a highly contagious disease. The immune suppression regimen is progressively diminished so that in about 8 weeks the patient has not only come out of isolation, but is discharged from the hopsital; however, he or she must remain on immune suppressive medications for life.

17. The patient must be watched carefully for evidence of rejection of the transplanted heart, particularly so during the early weeks. External techniques, such as the electrocardiogram and careful physical examination, can give some indication of forthcoming rejection. The most reliable way of looking for incipient rejection is by biopsying the heart, a procedure which can be done under local anesthesia by advancing an instrument through the right jugular vein into the right heart chamber and obtaining tiny specimens of the heart muscle. This is done by Stanford on a weeky basis during the early postoperative period.

18. For the first six months patients are seen at weekly and then bi-weekly intervals at Stanford. Thereafter they are seen at 2 to 4-week intervals by their local physicians, who receive extensive instructions from Stanford. Patients must still return to Stanford annually for a two-day evaluative hospitalization.

19. Patients quite often have a rejection flare-up in the early weeks or months following transplantation; this is generally managed successfully by a temporary increase in medications. Continued treatment and surveillance are necessary because the tendency for rejection persists; there is on the average one episode a year requiring a temporary step up of the immunosuppressive drugs. There is also a greater susceptibility to infections and there is a serious infecton about every 15 months on the average. The immunosuppressive therapy is adjusted as low as possible to minimize infection and other side effects, yet high enough to avoid rejection - a delicate balance.

20. The quality of life of survivors is generally quite good. Patients must adhere to a lifelong theapeutic regimen, and they must remain under a doctor's care. However, ninety percent are considered rehabilitated. Some live an active retired life; most go back to school or work.

Peter L. Frommer

Peter L. Frommer, M.D.

cc: Dr. Fredrickson
Dr. Levy

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

TO : Director, Coverage Assessment Staff
National Center for Health Care Technology

DATE: January 21, 1980

Through: Director, National Center for Health Care Technology

FROM : Deputy Director, NHLBI

SUBJECT: Possible NHLBI Assistance to HCFA Regarding Cardiac Transplantation Coverage

We all appreciate that NHLBI is not, should not and will not be in the business of regulation. However, we do recognize that our recommendations include some which may not be down the mainstream of HCFA experience. NHLBI would be pleased to discuss with HCFA ways in which we may be of assistance in the carrying out of the recommendations in the accompanying memorandum on "Medicare Coverage of Heart Transplants."

Peter L. Frommer

Peter L. Frommer, M.D.

cc: Dr. Fredrickson
Dr. Levy

APPENDIX 1-B

JUNE 2, 1980 MEMORANDUM FROM
DR. PETER L. FROMMER

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

TO The File

DATE: June 2, 1980

FROM Deputy Director, NHLBI

SUBJECT: Highlights of Meeting of Consultants on Criteria for Cardiac Transplantation for HCFA

1. On May 27, 1980, nine consultants and a resource person, with several Federal observers in attendance (attachment 1) convened to address the criteria by which decisions should be made about institutions and patients for whom cardiac transplantation should be reimbursed by HCFA.

2. The consultants were unanimous in their judgment that cardiac transplantation was an effective, safe, and reasonable procedure in those end-stage cardiac disease patients in whom it is currently being done.

3. With respect to patient selection criteria, it was noted that those in use at Stanford have been developed to maximize the likelihood of a successful long-term outcome. However, it was noted that for the purposes of HCFA, these criteria must be stated more generally and exclusively in terms of enhancing the likelihood of successful medical outcome.

4. For HCFA approval of institutions and patient management protocols suitable for reimbursement, the judgment was that HCFA should not freeze the current procedures of one institution into regulations. Rather HCFA regulations should spell out the criteria by which applicant institutions will be reviewed, particularly in terms of the experience, resources, commitment, and plans of an institution - e.g., with such other organ transplantation as kidneys; in critical areas of professional expertise, such as cardiology, cardiovascular surgery, anesthesiology, immunology, bacteriology, infectious disease, nursing, neurology/neurosurgery, social service; the logistics for the overall transplantation procedure; and the plans for patient management. Such applications and plans would have to be subject to expert peer review. Implicit in the discussion was the need for periodic peer group reexamination of the outcome, ongoing activities, and future plans of institutions, presumably at several year intervals.

5. A central collection of relevant information about patient characteristics, procedures, and outcomes was deemed of great value.

6. It is my plan to submit to NCHCT recommendations for HCFA criteria for cardiac transplantation reimbursement by June 23.

Peter L. Frommer

Peter L. Frommer, M.D.

cc: Dr. Perry
Dr. Fredrickson
Dr. Levy
Dr. Towery
Dr. Lowe

May 27, 1980

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file copy 222-J

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

TO Director
National Center for Health Care Technology

DATE: June 27, 1980

FROM Deputy Director, NHLBI

SUBJECT: NHLBI Recommendations for HCFA Criteria for Selection of Institutions for Medicare Reimbursement for Cardiac Transplants

1. The attached document has been prepared after considering the discussions of the May 27 meeting on this topic. I hope you find tne materials useful.

2. We would be pleased to help further, within reasonable limits, to help resolve these sensitive topics.

Peter L. Frommer, M.D.

Attachment

cc: Dr. Fredrickson
Dr. Levy
Dr. Lowe
Dr. Towery

bcc: Dr. Moskowitz
Dr. Friedewald
Dr. Packard
Dr. Mock
Dr. McCallum

6/27/80 - PLF

HCFA CRITERIA FOR REIMBURSEMENT FOR CARDIAC TRANSPLANTATION

1. Proposed rules are set forth below whereby HCFA will make decisions on the acceptance of patient care costs for cardiac transplantation.

2. Cardiac transplantation cannot be considered as simply a surgical procedure. Clinical effectiveness and usefulness - and therefore HCFA decisions on reimbursement - are dependent upon careful and appropriate patient selection, expert surgery, postoperative care, immunosuppression, evaluation for incipient rejection of the donor heart, management of complications associated with immunosuppression, and advice and working with the patient and his or her permanent physician on the patient's subsequent lifelong care.

3. Because of the unusual complexities and needs for achieving effective, safe, and reasonable clinical results with cardiac transplantation, cardiac transplantation will be reimbursed only according to the regulations set forth below.

4. For the purposes of these regulations, Phase I of cardiac transplantation includes those facets associated with the hospitalization for the transplantation procedure and its immediately juxtaposed intensive outpatient management conducted by the team from the transplanting institution, i.e., the definitive selection of patients, the surgical procedure, postoperative care, immunosuppression, monitoring for incipient rejection of the donor heart, management of any early complications, and the early outpatient phase of management in immediate juxtaposition to the main hospitalization involving frequent outpatient visits and conducted by the team of the transplanting institution.

5. For the purposes of the regulations, Phase II of cardiac transplantation refers to the subsequent lifelong management of the heart, immunosuppression and possible complications of immunosuppression of the patient who has received the cardiac transplant.

6. Medicare coverage for Phase I of cardiac transplantation will be limited to selected institutions. This is dictated by the complexity of the procedures, the need for skilled and specially experienced physicians and surgeons from multiple disciplines, the availability of special resources, logistical considerations, the need for institutional commitment, efficiencies, and the need to concentrate experience. The procedures and criteria for selection of such institutions are set forth below beginning in paragraph 10.

7. Medicare coverage for Phase II is not restricted to institutions selected for participation in Phase I, but it must be done in consultation with an institution selected for Phase I participation.

8. Only patients otherwise eligible for Medicare are eligible for reimbursement for cardiac transplantation of either Phase I or Phase II.

9. Medicare coverage for diagnostic studies to assess the severity of cardiac disease in potential recipients of a transplant is not restricted to institutions which have been selected for participation in Phase I.

10. Institutions at which Phase I will be accepted for Medicare reimbursement will be selected by HCFA with the aid and advice of a panel or panels made up predominantly of experts in the fields of cardiology, cardiovascular surgery, organ transplantation, and immunology.

11. Meetings of such a panel or panels shall be scheduled at not less than six-month intervals, and applications from institutions seeking coverage for Phase I which are received by HCFA within two months prior to the published date of the meeting shall be reviewed at that meeting.

12. The expert panel shall examine written materials submitted by the applicant institution; it may seek additional relevant information as deemed necessary, for example, through site visit to the applicant institution and interviews with relevant persons.

13. The expert panel need not conduct the deliberations by which it comes to its judgment in open meeting, but appropriate Government staff must be present, and the bases for the conclusions and recommendations of the expert panel must be in the form of a written document.

14. The expert panel will take into account the medical experience in cardiac transplantation at the time of its meeting. As of this date, the clinical experience involving the largest series of patients (that from Stanford University) will serve as a benchmark with respect to patient selection, management, and expected outcome. The expert panel will not automatically restrict itself to institutions adhering to the same patient selection criteria or the same patient management protocols as the benchmark series. The expert panel will make its recommendations on the basis of the evidence set forth by the applicant institution and the expert panel's assessment of medical experience.

15. Applicant institutions will be judged according to the following criteria:

A. Adequacy of patient selection criteria.

(1) Patient selection criteria must be presented which are based upon both critical medical need for transplantation and maximum likelihood of successful clinical outcome.

(2) The patient must have a very poor prognosis (e.g. less than 10 to 25% likelihood of survival for six months) as a result of poor cardiac functional status.

(3) All other medical and surgical therapies must have been considered and/or tried which might be expected to yield an early and one-year survival comparable to that of cardiac transplantation.

(4) Many factors are recognized at the present time to exert an adverse influence on the outcome after cardiac transplantation. Strongly adverse factors include:

(a) advancing age - e.g., beyond 50 or the early 50's (because of diminished capacity to withstand postoperative complications),

(b) severe pulmonary hypertension, for example, as reflected by a pulmonary artery systolic pressure over 65-70 mm Hg and exceeding pulmonary artery wedge pressure by about 40 or more mm Hg, or a calculated pulmonary vascular resistance above approximately 6 Wood units (applicable to orthotopic cardiac transplantation because of the limited work capacity of a normal donor right ventricle),

(c) irreversible and severe hepatic or renal dysfunction (because of the likelihood of exacerbation early postoperatively and because of interference with immunosuppressive regimens),

(d) active systemic infection (because of the likelihood of exacerbation with initiation of immunosuppression),

(e) any other systemic disease considered likely to limit or preclude survival and rehabilitation after transplantation,

(f) a history of a behavior pattern or psychiatric illness considered likely to interfere significantly with compliance with a disciplined medical regimen (because a lifelong medical regimen is necessary requiring multiple drugs several times a day with

serious consequences in the event of their interruption or excessive consumption),

Other adverse factors include:

(g) recent and unresolved pulmonary infarction or pulmonary roentgenographic evidence of infection or of abnormalities of unclear etiology (because of the likelihood of pulmonary infection or its exacerbation with initiation of immunosuppression under such circumstances),

(h) insulin-requiring diabetes mellitus (because of exacerbation by chronic corticosteroid therapy),

(i) symptomatic or documented severe asymptomatic peripheral or cerebrovascular disease (because of observed accelerated progression in some patients after cardiac transplantation and on chronic corticosteroid treatment),

(j) active peptic ulcer disease (because of the likelihood of early postoperative exacerbation),

(k) the absence of adequate external psychosocial supports for either short or long-term bases (because such support is generally necessary during the inevitable waxing and waning of the clinical status of the patient and for adherence to the lifelong medical regimen).

B. Adequacy of patient management plans and protocols.

(1) The detailed plans for the therapeutic and evaluative procedures for the acute and long term management of a patient, including commonly encountered complications.

(2) The basis for confidence in the proposed therapeutic and evaluative regimen.

(3) The logistics of the plans for patient management and evaluation during the waiting and immediate post discharge, as well as in-hospital phases of the program - i.e., all facets of Phase I.

(4) The logistics of the plans for long-term management and evaluation, including education of the patient and liaison with the patient's permanent physician - i.e., all facets of Phase II.

C. Institutional commitments, resources, experiences, and plans.

(1) Commitment of the institution at all levels and broadly throughout the institution. (A cardiac transplantation program requires a major commitment of resources. These may temporarily include many other departments as well as the principal sponsoring departments.)

(2) Expertise and commitment for participation in the medical, surgical, and other relevant areas, particularly cardiology, cardiovascular surgery, anesthesiology, immunology, infectious diseases, nursing, neurology/neurosurgery, and social service. In most of these areas, individual persons need to be identified to achieve an identifiable and stable transplant team.

(3) The component teams must be integrated into a comprehensive team with clearly defined leadership and corresponding responsibility.

(4) Experience with a clinical organ transplantation program involving immunosuppressive techniques and the results of that program(s). In the absence of such an active clinical organ transplant program, there will be great difficulty in showing that the necessary expertise will be available, regularly experienced, and logistically feasible.

(5) An active cardiovascular, medical, and surgical program as evidenced by a minimum of 500 cardiac catheterizations and coronary arteriograms annually with the ability and willingness to do such procedures on an emergency basis. The surgical group must have demonstrated acceptably low mortality rate in an active open heart surgical program involving at least 250 procedures a year. The surgical team responsible for transplantation must be an identified, stable group.

(6) Anesthesia must be prepared to develop a team for transplantation that will also be available at all times.

(7) The infectious diseases service must have both professional skills and the laboratory resources that are needed to discover, identify, and manage a whole range of organisms, many of which are uncommonly encountered in the usual infectious diseases laboratory.

(8) The nursing service must be prepared to develop a team or teams trained not only in hemodynamic support of the patient, but also in the special problems of managing immunosuppressed patients.

(9) Pathology resources must be available for studying and promptly reporting the pathological responses to transplantation.

(10) A neurology or neurosurgery group must be available for the donor selection procedures for objective clinical decision on brain death.

(11) Adequate social service resources must be available.

(12) There must be a clearly assigned and knowledgeable legal officer familiar with transplantation laws and regulations.

(13) Adequate logistical plans must exist for organ procurement meeting legal and ethical criteria, as well as yielding viable transplantable organs in reasonable numbers.

(14) Overall institutional plans, commitments, and resources must be available for a program which can assume a dimension large enough to assure a reasonable concentration of experience, e.g., 12 or more cardiac transplantation cases per year. (It is not necessary that this level of activity be achieved or maintained, but it must be shown to be feasible on the basis of plans, commitments and resources.)

D. Willingness to submit data to a central data registry.

(1) There must be willingness to submit summary data, in standard format, about patients selected, procedures used and short and long-term outcome on all patients undergoing the transplantation procedure, not only those for whom Medicare reimbursement is obtained. (Such data are necessary to provide a data base for an ongoing assessment of cardiac transplantation.)

16. Approval of an institution for participation in Phase I of cardiac transplantation under Medicare shall ordinarily be given for a period of not less than three nor more than five years. A staff review of an approved institution shall take place annually involving at least the central registry data described above. Renewal of approval will be with the assistance of an expert peer group, reviewing the experience and further plans of the institution.

17. Approval for participation in Phase I cardiac transplantation may be rescinded at any time at an individual institution for cause, or it may be rescinded as a total program at all institutions.

CHAPTER 2

RENAL TRANSPLANTATION: THE PROTOTYPE

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A. A BRIEF HISTORY OF RENAL TRANSPLANTATION

Experience in heart and liver transplantation followed chronologically that of kidney transplantation (Lower and Shumway, 1960; Starzl, 1981). In this regard, clinical renal transplantation served as the prototype. As with most clinically performed procedures in man, however, much of the preliminary work was performed experimentally in the laboratory. The events leading up to and then following the first renal transplant in man are instructive because they provide some insight into the process by which experimental procedures gain therapeutic status and value.

The history of renal transplantation has been considered at great length elsewhere. Only the more significant landmarks are discussed here. Much of the experimental work is omitted from consideration (Groth, 1972; Merrill, 1981; Murray, 1981; Dammin, 1981; Goodwin, 1981; Moore, 1965; 1972; Starzl et al., 1968; Starzl, 1964; Merrill et al., 1984; Starzl, 1984).

The earliest known attempt to treat uremia by anastomosing a renal graft to the circulatory system was made by Ullmann in 1902. Ulmann's work was presented at a meeting held on January 24, 1902 in Vienna. Ullmann emphasized that it was possible to carry out kidney transplantation by direct vascular anastomosis. At the conclusion of the meeting he outlined his next experiments as follows (cited in Moore, 1972:68):

> Further experiments will show whether kidneys can be transplanted from one dog to another, whether the kidney of one species of animal can be transplanted into another species and still retain its physiological function, and even whether (though it scarcely seems possible) transplanted kidneys can take over the burden

> of the entire blood-purifying process, i.e., whether the animal will remain alive if its own kidneys are removed and the transplanted ones are the only ones to function.

Several months later at the next meeting of the local surgical society on June 27, 1902, Ullmann discussed the results of his more recent experiments. He commented as follows (cited in Moore, 1972:68-69):

> I was unsuccessful at first in transplanting a kidney from one species of animal to another, but I am able to demonstrate to you today before this distinguished audience, a goat into whose neck region the kidney of a dog has been transplanted. You can see that the kidney is functioning completely normally and that urine is flowing in drops from the end of the protruding ureter. I must frankly admit that the success of this experiment surprised even myself. Although it has been known for a time that an excised kidney, when perfused with foreign blood, soon resumes secretion, I did not really believe that this would be the case in a living animal; this opinion was shared by all experts.

Shortly after this time Ullmann abandoned his transplantation studies, but the work he had completed was of great significance to those who followed him.

It was not until four years later that the next surgical success was reported by Jaboulay (1906). He anastomosed kidneys from a pig and goat, respectively, to an artery and vein in the arms of two patients. Diuresis lasted approximately one hour, the grafts ceased to function and they were removed a few days later.

In 1904 Carrel carried out his first work on kidney transplantation in Chicago. The first publication on his work appeared in Science in 1905 and was co-authored by Guthrie. In this paper they described the transplantation of a kidney from the flank into the neck of the same

dog. They were able to demonstrate the feasibility of the operation, and that the transplanted kidney could function satisfactorily. The following year Carrel and Guthrie (1906) published a second paper on kidney transplantation that described the procedure that was later to become prototypical. Further reports were published by Carrel over the next four years (Carrel, 1908; 1910). In 1910, he summarized his work on kidney transplantation and focused clearly on the central problem of the contrast between allografts and autografts. He wrote (cited in Moore, 1972:73):

> Should an organ, extirpated from an animal and replanted into its owner by a certain technique, continue to functionate normally, and should it cease to functionate when transplanted into another animal by the same technique, the physiological disturbance could not be considered as brought about by the surgical factors. The changes undergone by the organ would be due to the influence of the host, that is, biological factors.

In 1910, Unger (1910) made still another attempt at xenografting by placing both kidneys in the groin of a uremic patient. Although the graft proved unsuccessful, some progress was made in the technical aspects of renal transplantation. An intracorporeal location was used for the graft and the desirability of genetic similarity between donor and recipient was recognized. Groth (1972) notes that a few other attempts were made to transplant kidneys from the monkey (Morel and Papin, 1913) and the lamb (Neuhof, 1923).

A Russian surgeon, Voronoy (1936) was the first to report the use of a renal transplant from a human donor. The kidney used in the procedure had been obtained from a recently deceased person. It was anastomosed to the femoral blood vessels of the recipient, who was

suffering from mercury poisoning. Although the graft produced small amounts of urine for two days, on the third day the patient died. In 1945, Lundsteiner and Hufnagel (cited by Hume, 1955) made a similar attempt, but the transplanted kidney failed to function and the patient's own renal function improved. The transplant was removed in 48 hours.

Lawler and his co-workers (1950) in Chicago were the first to describe a clinical renal transplantation in a intra-abdominal location. The patient suffered chronic uremia, and the operation was undertaken to obtain lasting improvement of renal function. This transplant was somewhat successful, since it was not until seven months later that the kidney ceased to function (Lawler et al., 1951). The transplant procedure was described by Lawler et al (1950:844) as follows:

> On June 17, 1950 the patient was brought to the operating room and the left polycystic kidney was removed. A kidney removed from a white woman 49 years of age, with identical blood type, who had just died after hemorrhages from esophogeal varices and cirrhosis of the liver, was transplanted into the host. In preparation for the transplantation the donor's kidney, immediately after its withdrawal from the body, had been bathed in saline solution and the blood expressed by gentle pressure and aspiration. Heparin plus saline solution had then been injected into the artery and vein. The ureter had been allowed to remain attached to its fatty surrounds in order not to disengage its blood supply.
>
> After the transplantation an end to end anastomosis of the renal artery and renal vein was accomplished using four-0 black silk sutures. The proximal renal vessels were held with bulldog type clamps until the anastomosis was completed. When the clamps were removed, the vessels filled immediately with blood and the color of the kidney changed from bluish brown to reddish brown. The ureter was then anastomosed to the host's ureter by an end to end approximation around a small catheter. This catheter was brought out through

> the kidney pelvis and thence out through the incision so that after healing had occurred at the anastomosis it could be withdrawn. Nephropexy was not done, the kidney being placed in the perirenal tissues and held only at the renal vessels and at the ureter. A large gauze pack was used to further hold the graft in place temporarily and to control any oozing at the operative site. The incision used was that usually employed from nephrectomy extending across the flank with a retroperitoneal approach.
>
> The immediate postoperative course of the patient was uneventful. The urinary output was within normal limits, and some days the urinary output exceeded the measured intake of fluids.

In 1951, Groth (1972) reports that no fewer than eight attempts at renal transplantation in human beings were attempted in France. One of these was by Servelle and his associates (1951a; 1951b), two by Dubost and his colleagues (1951a; 1951b), and five by Kuss and his co-workers (1951). In each of these cases, the procedures followed were much like they are today--the graft was placed in the iliac fossa, and the renal artery and vein were anastomosed to the iliac blood vessels. Kuss and his associates (1951) were the first to use living donors. These transplants could not be judged successful since in no instance did the patient's uremic condition improve.

The Peter Bent Brigham Hospital had instituted a dialysis program to treat renal patients before the first renal transplant was performed there in 1952 (Hume et al., 1952). Prior to this time, however, a renal dialysis patient at Brigham received a kidney transplant at the Springfield Hospital where the procedure was performed by Scola (Hume et al., 1955; Moore, 1972:86). In March, 1951, Scola removed a kidney from a patient suffering from cancer of the ureter. The kidney had to be removed to treat the cancer. The

transplant was performed in a rather unusual way, the renal artery was joined to the splenic artery after removal of the spleen.

Scola (cited in Moore, 1972:86-87) subsequently described the transplant as follows:

> The donor was a 49 year old man who had to lose a good kidney due to a tumor of the lower left ureter and his blood crossmatched with that of the recipient.
>
> In considering the problems that might be encountered at operation, one strong possibility was that the recipient's renal artery may be narrowed (not infrequent in severe kidney disease) or may be multiple and small and not match the donor's vessels. Therefore, I was prepared to remove the spleen and swing the artery down to the renal area. This is exactly what happened at operation on March 31, 1951, because the recipient's renal artery was atrophic. When I discovered this I entered the peritoneal cavity and easily brought the splenic artery retroperitoneally to the left renal fossa. The donor's renal artery was injected with heparin just prior to clamping (another team operated on the donor). After the anastomosis was completed the recipient's renal artery was injected with heparin.
>
> The transplanted kidney was without blood supply for 70 minutes.

Following the operation the patient was sent back to Brigham hospital where he died on May 7, 1951 from renal failure, after failing to respond to dialysis.

On April 13, 1951 Hume undertook his first renal transplant at the Brigham (Moore, 1972:89). Several transplants were performed subsequent to this one with donor kidneys coming from "...bodies of recently deceased individuals or young people who had to lose a kidney anyway during treatment for a condition known as 'hydrocephalus'." No kidneys were removed from healthy people unless the kidney would have otherwise had to have been removed.

In all of these early experiments patients inevitably succumbed to rejection after brief periods when the new kidney "lived and breathed." Uremia was frequently reversed, and rejection occurred at a much slower rate than it did in dogs.

By 1953, Hume and his associates (1955) had performed eight more renal transplantations with free or cadaveric kidneys. The procedure followed in these cases differed from that of the French. The renal blood vessels were anatomosed to the femoral artery and vein, and the kidney was placed subcutaneously in the upper part of the thigh. None of these patients regained complete renal function, although they did exhibit some clinical improvement.

On February 11, 1953 Hume performed what was to be the most successful renal transplant up until that time. It was his ninth. After a stormy postoperative course, the patient's wounds healed, the kidney began to perform well, and the patient was able to get out of bed and move about. The patient was discharged from the hospital on the eighty-first day after the transplantation and, as noted by Moore (1972:90), was "...the first patient in history to be discharged out of the hospital living solely on the function of a kidney taken from another person."

The patient returned to the hospital for regular checkups, but after the one hundred-third day his blood pressure was elevated and drug therapy proved unsuccessful. Five months and 25 days after the transplantation, the patient died rather suddenly from renal failure and severe high blood pressure (Moore, 1972:91). It was this experience that directed attention to the need for bilateral

nephrectomy in the treatment of patients with chronic glomerulonephritis if a kidney transplant was to be successful.

All these early transplants were performed in unmodified (non-immunosuppressed) patients. It was at this point, following the departure of Hume to become Professor and Head of the Department of Surgery at the Medical College of Virginia, that Murray, after successfully modifying the technical nature of the transplant procedure, began some work that had immunological significance, even though he went on to perform six additional transplants without any help from drugs or irradiation. This brought the total number of such patients to 15. All total, fourteen other transplants of free or cadaveric kidneys were undertaken in Boston (Murray et al., 1962), Los Angeles (Goodwin et al., 1962), Cleveland (Krieg et al., 1960), and London (Hopewell et al., 1964; Joekes et al., 1957; Porter et al., 1963) in the middle and late 1950s. None of the patients in these series achieved life sustaining renal function. Primary reasons for failure were grafts damaged by prolonged ischemia, technical complications, and rejection.

Initial attempts were made by Dubost et al. (1951a; 1951b), Kuss (1951), and Hume et al. (1955) to address the rejection problem through the application of adrenocorticotropic hormone and cortisone, although to no avail. Groth (1972) summarized these early results as follows: "Thus, of 36 reported homotransplantations of free or cadaveric kidneys performed without effective immunosuppression, only one significantly prolonged survival of the recipient."

All donors in these initial renal transplants were unrelated to the recipients. Michon and his co-workers (1953) performed the first

renal transplantation in which the donor was a healthy relative in 1953. In this instance, it functioned well for 22 days when diuresis suddenly ceased and the patient died shortly thereafter. The pathological findings showed pronounced rejection of the transplanted kidney. These findings were discouraging.

By the mid-1950's it was generally felt that successful renal transplantation was possible only if the immune system could be suppressed to prevent rejection. At the time it was recognized that perhaps only a single situation may exist where immune responses could be eliminated from consideration. This was in the single instance where transplantation, in this case skin, occurred between monozygotic twins (Brown, 1937). At the time, however, there were serious concerns about the removal of a kidney from a healthy individual to transplant into a person with uremia. Groth (1972) notes that in Boston sufficient experience had been gained to justify taking this step. On December 23, 1954, Murray and his associates (Merrill et al., 1956; Murray et al., 1955) undertook the first renal transplantation between monozygotic twins. Moore (1972:101) describes the initial postoperative course of the patient as follows:

> After the operation the sick man recovered rapidly. Before the operation his heart had been enlarged, and there was fluid in his lungs. Within a few weeks the heart had decreased in size, the fluid in the lungs cleared, and clinical progress was good with return of appetite, strength and vigor. The piling up of waste products in the blood, so noticeable by elevation of the blood urea, soon returned to normal. The urine volumes were normal. Within a month the patient was on the road to convalescence.

The patient survived with good renal function for eight years, before dying from myocardial infarction. Murray and associates (1958) went

on to perform seven isotransplantations, and, during the next several years, similar operations were performed elsewhere.

The next era of renal transplantation had less to do with technique than with immune suppression. By 1958 total body irradiation was introduced at the Peter Bent Brigham Hospital (Murray et al., 1960) and later by Hamburger and his associates (1959). Shortly thereafter pharmacologic immunosuppression was introduced. Experimental studies in the late 1950's showed that the antimetabolite mercaptopurine could induce immunologic tolerance (Schwartz and Dameshek, 1959) and prolong the survival of canine renal homografts (Calne, 1960). Calne was the first to administer this agent to a human transplant recipient (Hopewell et al., 1964).

The next development in immunosuppression was the discovery, in 1961, that azathioprine, an analogue of mercaptopurine, had a superior immunosuppressive effect (Calne, 1961). During the same year the Peter Bent Brigham Hospital proceeded to adopt this agent for clinical use (Murray et al., 1962). It was during this period that the first cadaveric graft continued to function for more than 12 months (Merrill et al., 1963; Murray et al., 1963).

Further developments in the field of transplantation were pioneered by Starzl (Starzl et al., 1963a; 1963b; Terasaki et al., 1966) in Denver and Hume (Hume et al., 1966) in Richmond. Starzl introduced combination immunosuppressive therapy consisting of azathioprine and prednisone. All but one of the patients in this series had excellent renal function two to seven months after transplantation. As it turns out, this was the first series in which good results were obtained in the majority of the patients.

Terasaki and his colleagues (1966) were the first to implement histocompatibility testing as a method of selecting the most immunologically suitable of several donors in 1964. At approximately the same time, Hume and his co-workers (1966) demonstrated that, with adequate immunosuppression,long-term survival could also be achieved in cadaveric organ transplant recipients. Graft failure rates, nonetheless, remained high. Also, Hume was the first to demonstrate the feasibility of retransplantation.

Further achievements were made in the field of organ transplantation, including the development of additional immunosuppressive techniques. These are further discussed in Chapter 4, but the landmarks of renal transplantation, including some not discussed here, are presented in Table 2-1. As shown here, the major developments of the 1960's were immunological. Further breakthroughs in transplantation are also likely to be immunological, the most recent of which has been cyclosporine (Starzl et al., 1983; Griffith et al., 1983; Oyer et al., 1983; Merion et al., 1984; Stiller et al., 1983; Macek, 1983; Evans, 1984; Sutherland et al., 1984).

B. THE CURRENT STATUS OF RENAL TRANSPLANTATION

In recent years renal transplantation has enjoyed great success. Results have improved considerably, not only for living related donor transplants, but also for cadaveric transplants (see Table 2-2). Moreover, renal transplantation is now being offered to patients previously considered at high risk, namely diabetics (Sutherland et al., 1982; van Schilfgaarde et al., 1984). Thus, it is not surprising that over the years the number of transplants performed each year

Table 2-1
Landmarks In Renal Transplantation

KEY PERSON	CITY, DATE	EVENT	REFERENCES
Lawler	Chicago, 1950	First report of a transplant in which the patient had chronic uremia and the kidney was transplanted intraabdominally	Lawler et al., 1950; 1951
Hume	Boston, 1953	First transplantation in which the kidney effected adequate diuresis for several months	Hume et al., 1955
Michon	Paris, 1953	First transplantation of a kidney from a close relative; excellent, but short-lived function	Michon et al., 1953
Murray	Boston, 1954	First transplantation between monozygotic twins; good, lasting function	Murray et al., 1955
Murray	Boston, 1959	First homotransplantation after irradiation of the total body in which two patients survived several years	Murray et al., 1960
	and		
Hamburger	Paris, 1959	(ditto above)	Hamburger, et al., 1959
Murray	Boston, 1961	First use of immuno-suppressive drug azathioprine in clinical renal transplantation	Murray et al., 1962

Table 2-1 (Continued)
Landmarks In Renal Transplantation

KEY PERSON	CITY, DATE	EVENT	REFERENCES
Starzl	Denver, 1963	Homotransplantation of intrafamilial kidneys and immunosuppression with azathioprine and prednisone for the first time provided good results in a majority of patients	Starzl et al., 1963b
Terasaki	Los Angeles, 1964	First application of histocompatibility tests to select the most suitable donor-recipient combination	Terasaki, et al., 1966
Franksson	Stockholm, 1964	Drainage of lymphocytes through the thoracic duct used for the first time as an immunosuppressive method in human beings	Franksson, 1964
Starzl	Denver, 1966	Antilymphocyte globulin used for the first time as an immunosuppressive agent in clinical transplantation.	Starzl et al., 1967

SOURCE: Groth, 1972.

Table 2-2
Patient and Graft Survival Rates for Kidney Transplant Recipients According to Source of Graft

	UNRELATED DONOR	RELATED DONOR
PATIENT SURVIVAL RATES		
Survival at 1 Year	86 ± 0.4%*	95 ± 0.4%
Survival at 3 Years	78 ± 0.5%	91 ± 0.6%
GRAFT-RETENTION RATES		
Graft Retained 1 Year	56 ± 1.0%	75 ± 1.0%
Graft Retained 3 Years	45 ± 1.0%	67 ± 1.0%

*The plus or minus values are standard errors.

SOURCE: Kraukauer et al., 1983.

has increased. As shown in Table 2-3, between 1951 and 1962 only 75 kidney transplants were performed. By 1970, this number increased to just over 1,000 and by 1983 it totaled 6,112. Major increases in the number of procedures performed roughly coincides with major developments in the field, such as the identification of new and effective immunosuppressive agents. It is now believed that over 15,000 people are alive who have functioning grafts, and this number is sure to increase over the next several years as patient survival rates improve (Krakauer, 1983). Transplant patients now comprise 17.1 percent of all people who are currently undergoing some form of treatment for end-stage renal disease (see Table 2-4).

There are currently 159 kidney transplant centers in the U.S. In 1983, these centers performed over 6,100 transplants. A complete summary of kidney transplants by year (for the last seven years) according to source of donor is provided in Table 2-5. While the number of living related donor transplants has increased since 1979, it is quite possible this number will decline in the future. Several transplant surgeons are now suggesting that because of cyclosporine and the "...outstanding results obtained with cadaveric transplantation, the use of living donors has lost much of its attractiveness" (see Starzl et al., 1983; 1982; Belzer et al., 1984). Others have disagreed with this contention. For example, Najarian and co-workers (1983:2467) have commented as follows:

> Some groups have stated that the availability of CsA (cyclosporine) has diminished the advantage of using related donors for kidney transplantation. We disagree. We included kidneys from related and cadaver donors in our trial, and, in the CsA group, related donor kidneys had a better survival rate than cadaveric grafts (94%

Table 2-3
Number of Patients Receiving Kidney Transplants By Year

YEAR	TOTAL NUMBER OF KIDNEY TRANSPLANTS PERFORMED EACH YEAR	
1951-62	75	
1963	163	
1964	239	
1965	305	
1966	338	
1967	448	
1968	676	
1969	838	
1970	1,091	(1,460)[a]
1971	1,616	(2,909)
1972	1,993	(2,852)
1973	3,017	
1974	3,190	
1975	3,730	
1976	3,504	
1977	3,973	
1978	3,949	
1979	4,271	
1980	4,697	
1981	4,883	
1982	5,358	
1983	6,112	

*Numbers in parentheses reflect discrepancies in the literature.

SOURCE: OTA, 1982; HCFA, 1980; 1981; 1982; in press;
M. McMullan, personal communication, 1984.

Table 2-4
Distribution of ESRD Patients by Modality, 1983

DIALYSIS	NUMBER	PERCENT
In-Center Hemodialysis	57,031	65.5
Home Hemodialysis	4,323	5.0
CAPD	8,532	9.8
Intermittent Peritoneal Dialysis	1,535	1.8
Dialysis Training	607	.7
SUBTOTAL	72,028	82.9
TRANSPLANTATION		
All Functioning Grafts*	15,000	17.1
TOTAL	87,028	100.0

*These figures are estimates (from Krakauer, 1983) derived from what is known about the survival of transplants and the number performed each year (see Garrison et al., 1983). Data on dialysis patients provided by M. McMullan, 1984.

Table 2-5
Annual Distribution of Kidney Transplants
By Source of Donor Organ (1977-1983)

YEAR	TOTAL TRANSPLANTS	LIVING DONOR		CADAVERIC DONOR	
		NUMBER	PERCENT	NUMBER	PERCENT
1977	3,973	1,495	37.6	2,488	62.4
1978	3,949	1,172	29.7	2,777	70.3
1979	4,189	1,186	28.3	3,003	71.7
1980	4,697	1,275	27.1	3,422	72.9
1981	4,883	1,458	29.9	3,425	70.1
1982	5,358	1,677	31.3	3,691	68.7
1983	6,112	1,784	29.2	4,328	70.8

SOURCES: HCFA, 1980; 1981; 1982; in press; M. McMullan, personal communication, 1984.

> vs. 83% functioning at 1 year), the same relative difference that occurred in the Aza (azathioprine) group (87% vs. 76%).

Due to the acute shortage of donors that prevails today, it is unlikely that living related donor transplants will be completely abandoned despite the suggestion (as yet unsubstantiated) that living-related donors experience decreased renal function over their life span (Brenner et al., 1982; Vincenti et al., 1983).

The Health Care Financing Administration's (HCFA) annual survey of dialysis and transplant centers reveals that there are many people awaiting transplants for whom suitable donor kidneys have yet to be found. Results of HCFA surveys for 1979 through 1982 are shown in Table 2-6. These figures are somewhat deceiving because some patients are counted twice; once at a transplant center and again at their dialysis center. Furthermore, some of these patients, due to presensitization, are unlikely to receive a transplant in the very near future. Other desperate patients, although not truly acceptable transplant candidates, are placed on waiting lists by nephrologists to give them hope. Despite these problems, it seems reasonable to conclude that approximately 6,700 patients are on transplant waiting lists.

Recently some renal transplant surgeons have de-emphasized tissue matching among cyclosporine-treated transplant patients. Dr. Barry Kahan at the University of Texas--Houston is particularly outspoken on this matter. Also, Starzl et al. (1983) have been equally outspoken, commenting upon and speculating about the future as follows:

> The importance of tissue matching at the A, B, and D loci will be reduced. Since cyclosporine cannot prevent hyperacute rejection, the importance of accurately

Table 2-6
Number of Persons Awaiting Transplant as Reported
by Kidney Dialysis and Kidney Transplant Centers

YEAR	TRANSPLANT CENTERS	DIALYSIS CENTERS
1979	4,883	6,410
1980	4,825	1,541
1981	5,584	1,677
1982	6,720	7,292

SOURCES: HCFA, 1980; 1981; 1982; in press.

> identifying preformed antidonor T-warm antibodies will be increased. As a corollary, it will become increasingly important to avoid sensitization of potential kidney recipients by deliberate transfusion. Because it has been so much easier to treat diabetics with the low steroid doses than are needed with cyclosporine, these patients have become more attractive candidates for cadaveric organs. Other patients of marginal candidacy will be more freely admitted to transplant waiting lists. The fact that the organ supply will become critical is quite obvious.

Despite the already obvious increase in the size of the potential recipient pool, transplant physicians have, once again, begun to openly criticize nephrologists for "sequestering" patients. Dr. Paul Terasaki recently noted that there are approximately 5,000 patients on kidney dialysis in the Los Angeles area but only 300 are currently on kidney transplant waiting lists (personal communication with Christopher R. Blagg, M.D.). While not all dialysis patients meet the selection criteria for transplantation, because of fear and numerous other reasons, sequestering of patients may be a problem where the profit motive is a primary consideration (Warren et al., 1982; Belzer et al., 1983). Most would agree, that in light of the foregoing, it will become imperative for the government to address the problems of need, supply, and demand for kidney transplantation.

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CHAPTER 3

HEART TRANSPLANTATION: A BOLD EXPERIMENT, NOW REALITY

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A. A BRIEF HISTORY OF HEART TRANSPLANTATION

While developments in heart transplantation cannot be viewed apart from developments in organ transplantation more generally, the history of heart transplantation is worthy of independent review. Shumway (1981; 1983; Shumway and Stinson, 1979), Baumgartner et al. (1979), and Griepp and Ergin (1984) have summarized the major events leading up to the first heart transplant in man. In doing so, they note that clinical heart transplantation was the result of decades of laboratory investigation dating back to the early part of the 20th century. Through considerable experimental laboratory work, several key problems were identified including: (1) design of simplified and routinely successful surgical techniques, (2) development of techniques to permit the successful preservation of the donor heart following excision from the donor, (3) documentation that the anatomically denervated heart could function satisfactorily following implantation in the recipient, (4) investigation into and development of methods for diagnosing and treating acute graft rejection, and (5) identification and control of the morphological consequences of the chronic immune reaction of the host to the transplanted heart.

Moore (1972), in his review of the development of cardiac transplantation, appears to disagree with those who felt that cardiac transplantation was the subject of a satisfactorily long period of experimental study before reaching the point of clinical application. He notes that, "Unlike transplantation of other organs, progressing cautiously after a slow laboratory launch, cardiac transplantation leaped into action suddenly, quickly getting off the ground, and basing its meteoric rise on remarkably brief laboratory studies." As

a result, even since its initial clinical application, the question most frequently asked is "...when is it advisable?" The early experiences with experimental cardiac transplantation seemed to provide only a very weak foundation for the reply "now."

It is true, as Moore (1972) argues, that heart transplantation can be credited with creating more publicity for transplantation science than the transplantation of any other organ. This has only recently been superceded, perhaps, by the transplantation of livers in pediatric recipients. This is not new in itself, since several renal transplant programs have aggressively pursued pediatric transplantation in recent years as the optimal form of treatment for very young patients with end-stage renal disease (Fine, 1981; 1982; Lum et al., 1982; D'Amaro et al., 1983; Trompeter et al., 1983). Up until recently heart transplant surgeons have been reluctant to perform transplants in pediatric patients. Following several recent pediatric heart transplants, attention has once again been directed to cardiac transplantation as the most dramatic of transplant operations.

The first cardiac transplantation was reported in 1905 by Carrel and Guthrie (1905) in the Hull Physiological Laboratory at the University of Chicago. As noted in Chapter 2, these same investigators were also actively involved in kidney transplantation. In their early work on heart transplantation, hearts were removed from puppies and sutured into the necks of adult mongrel dogs. Quite surprisingly, Shumway (1981) notes, despite the crude nature of the surgical instruments and suture materials used, some of the transplanted hearts functioned for several hours. As it turns out, Carrel and Guthrie collaborated only a few months before Carrel departed for the

Rockefeller Institute in New York and Guthrie for Washington University in St. Louis.

As described by Shumway (1981), the leading surgeons of the day, among them Halstead, John B. Murphy, Rudolph Matas, Harvey Cushing, Joseph Colt Bloodgood, and George Crile, although familiar with the work of Carrel and Guthrie, largely ignored it. It was during a meeting of the Society of Clinical Surgery in Chicago in 1905 when Harvey Cushing mentioned that a young Frenchman by the name of Alexis Carrel was doing some interesting work in the areas of surgical anastomosis and transplantation of blood vessels (Carrel, 1907). When, in 1912, Carrel received the Nobel prize in medicine and physiology, subsequent controversy waged as to the significance of Guthrie's contribution.

Following the pioneer work of Carrel and Guthrie, there was nearly a 30-year hiatus in experimental heart transplantation. It was not until the mid-1930s, when Mann and his associates (1933) at the Mayo Clinic, with the help of better surgical instruments, were able to transplant puppy hearts heterotopically and achieve survival up to eight days. Mann, unlike his predecessors, was able to distinguish between failures attributable to surgical technique and those resulting from some kind of biological manipulation or rejection. Mann noted that: "The general behavior of such a transplanted organ, the heart, with regard to function, period of survival, and cytologic changes, is similar to other homotransplanted organs." Reflecting on the efforts of Mann and his associates, Baumgartner et al. (1979) state that their work was really the beginning of efforts "...directed primarily toward modification and simplification of the techniques of heterotopic

cardiac transplantation." Moore (1972:258) summarized the nature of their work as follows:

> Their interest was in cardiac function when all nervous connections were severed, rather than its effectiveness as a unaided pump or as a problem of graft acceptance. They were studying short-term transplantation of only a few hours, placing the new heart in the neck, not essential to survival. Nonetheless, in the course of their work they discerned many aspects of cardiac transplantation that would acquire prominence thirty-five years later.

Activity in the field of experimental heart transplantation was to cease for the next twenty years. Shumway (1981) attributes this largely to the absence of immune suppression, a problem that has, of course, yet to be completely resolved.

In Russia, Demikov and Sinitsin developed techniques permitting the transplantation of donor hearts in a heterotopic but intrathoracic location so as to insert the graft in parallel with the recipient's heart in the circulation (Demikhov, 1950; 1960; 1962; Sinitsin, 1953). In most of Demikov's experiments, the donor heart was used as an auxiliary heart--blood was routed from the inferior pulmonary veins on the right into the transplanted organ, which pumped blood into the aorta (Shumway, 1981). Demikhov was able to demonstrate that, with proper anastomoses, it was possible to exclude the recipient's heart from the circulation and thus successfully transferred the entire circulatory load to the donor heart and achieve short-term survival. These remarkable results were achieved in the early 1950s, prior to the development of effective means for myocardial preservation and cardiopulmonary bypass. They set the scene for later clinical adaptation by Barnard and his coworkers in South Africa (Shumway, 1981).

It was in 1951 when Marcus and his group (1953) noted that while heart transplantation held some hope for the replacement of a hopelessly diseased organ, it amounted to little more than a fantastic dream.

Attempts at orthotopic heart transplantation of the canine heart were first reported by Goldberg et al. (1958) and Watts and Webb in 1958 (Webb and Howard, 1957a; 1957b; Webb et al., 1959). Watts and Webb's experiments included replacement of both the heart and right lung. Goldberg and associates met with limited success, their maximum survival time was 117 minutes. They did manage to identify several technical problems described in detail by Hairston (1965). Watts and Webb reported that twelve of their experiments were successful with ten showing maintenance of normal blood pressure from 30 minutes to 7.5 hours.

It was in the summer of 1958 that a group of investigators met at Stanford to take on the "challenge of orthotopic heart transplantation." By this time the most significant of transplant-related problems had been identified but were not yet fully understood. Even at this time, however, it was not possible to deal adequately with homograft rejection, even in the case of kidney transplantation, as discussed in Chapter 2.

Shumway (1981) notes that the easiest problem to resolve was the surgical technique. He describes the early techniques used in dogs at Stanford as follows:

> ...the Stanford group performed a left thorocotomy and inserted a cannula peripherally to afford unrestricted access to the heart. The heart was removed but left behind were generous segments of the atrial

> septum and both atrial walls. The several delicate venous anastomoses were simply combined into one long atriotomy for implantation of the donor heart.
>
> In 1958, elective cardiac arrest by means of potassium infusion at the base of the clamped aorta was widely practiced, as it is today, but with insufficient results. Since the heart is a shell rather than a solid organ, like the liver and kidneys, we speculated that local cooling to the heart might well accomplish most of the intracardiac manneuvers that were then being attempted in patients.
>
> Removing the donor heart and storing it in cold saline at two to six degrees centigrade clearly gave us the ultimate in selective cooling and provided not only a springboard for the transplantation experiments but also an improved means of dealing with clinical surgery.

These developments set the stage for the first fully successful orthotopic heart transplantation described by Lower and Shumway in 1960. Lower first presented his work on the subject at the American College of Surgeon's Clinical Congress in San Francisco, during the Surgical Forum sessions. Shumway (1981) remembers that early morning session as follows: "...(the) report was heard by the co-author (Dr. Shumway), the projectionist, and maybe the moderator."

The technique followed by Lower and Shumway (1960; Lower et al., 1961) has been described in detail elsewhere. Baumgartner et al. (1979) summarizes the technique as follows:

> The principal technical procedures culminating in this achievement included removal of both the recipient and donor hearts at the mid-atrial level (a manneuver that permitted rapid orthotopic implantation of the graft), myocardial preservation by simple hypothermia during interruption of the coronary circulation and reliable methods for cardiopulmonary bypass. Nearly routine long-term survival was obtained (Hurley et al., 1962a; 1962b; Lower et al., 1961; 1965).

Further study of simple hypothermia for myocardial preservation was required before it was applied directly in clinical cardiac

transplantation. In subsequent studies, the evidence accumulated in support of this technique not only for transplantation (Angell et al., 1969; Angell and Shumway, 1966; Lower et al., 1962; Copeland et al., 1973; Stinson et al., 1970) but also for routine cardiac procedures (Gott et al., 1960; Griepp et al., 1975; Greenberg and Edmonds, 1961).

The functioning of the denervated transplanted heart was studied in detail by Hurley and Dong. Invasive techniques demonstrated that the autotransplanted heart in dogs mimicked the orthotopic homograft in every way except for the absence of immune response. Cardiac catheterization studies revealed that the transplanted heart functioned normal or near-normal in both resting and stressful conditions.

Dating back to even the earliest experience in cardiac transplantation, graft rejection was a problem not at all unlike experiences with other solid organ transplants. The Stanford group, from the outset, documented the pathological characteristics of homograft rejection of the heart. Experience showed that untreated animals survived between 6 and 21 days. Shumway (1981) notes that in their early studies: "At two weeks, the host atrium was free of hemorrhage, whereas the donor atrium was hemorrhagic and edematous, a condition characteristic of rejection." There was no evidence that recipients of heart transplants survived longer than those receiving kidney transplants.

In orthotopic heart transplantation, rejection of the heart meant death. There was no artificial means by which life could be maintained. Thus, considerable attention focused on this problem during the early stages of laboratory experience with heart

transplantation. In 1962, it was shown that rejection of the canine heart was manifested by decreases in generated QRS voltage, as measured in standard ECGs (Lower et al., 1966; Lacassagne and Cachera, 1970; Semb et al., 1971). Ventricular arrhymias were also found to occur commonly during episodes of graft rejection. These observations proved to be the means by which rejection could be monitored noninvasively. Although not fully appreciated today, this was a profound development. Moore (1972:258) comments as follows: "Doctors had been struggling over laborious chemical measurements to discern kidney rejection, yet the heart presented the most elegant and frequent index of rejection: an electrical pattern traced with each heartbeat."

Extended survival of the transplanted heart was made possible by immunosuppressive drugs previously developed for the treatment of cancer and later used with success in the control of rejection in kidney transplantation (Murray et al., 1962). Reemtsma and his associates (1962; 1964) were the first to demonstrate prolonged survival of recipients of cardiac allografts by using immunosuppressive agents: first methotrexate and then azathioprine. Blumenstock and his colleagues (1963) using amethopterin for immunosuppression were able to achieve survival of orthotopic grafts in canine recipients for up to 42 days. Over time, further laboratory work has led to the development of additional immunosuppressive protocols that do not overly compromise the host making infection an inevitability (Hurley et al., 1962a; Lower et al., 1965; Kondo et al., 1974). The primary drugs now used in immunosuppression include prednisone, azathioprine,

antithymocyte antisera raised in various species (e.g., rabbit, horse), and cyclosporine.

The foregoing is the backdrop against which the first clinical experiences with cardiac transplantation took place. Multiple aspects of cardiac transplantation had been subjected to careful laboratory study. As noted by Baumgartner et al. (1979), "Surgical techniques had been refined, graft rejection had been characterized in terms of morphology and functional impairment, and long-term survival had been achieved with clinically applicable immunosuppressive drug regimens."

Prior to the first clinical heart transplant in humans, however, Hardy and co-workers in 1964, who had also carried out extensive experimental investigation of cardiac transplantation, reported on an unsuccessful attempt to transplant a chimpanzee's heart into a patient dying of end-stage hypertensive cardiac disease (Webb and Howard, 1957b; Webb et al., 1961; Lee and Webb, 1958; 1959; Kurrus et al., 1964; Hardy et al., 1964; Hardy and Chavez, 1969). The primate heart paced at a rate of 100 beats per minute at a blood pressure ranging from 60 to 90 mm Hg for approximately one hour after removal of the bypass catheters. At this point, "...the heart was judged incapable of accepting the large venous return without intermittent decompression by manual cardiac massage. Further support was abandoned even though a weak and regular beat continued." Based on their experience, Hardy and co-workers (1964) concluded that:

> This clinical heart transplantation in a most unusual set of circumstances lies within the established precedents of human transplantation of the nonpaired liver, the clinical transplantation of lower primate kidneys, and the exploration of mechanical ventricular support in a patient with terminal heart failure. Heart

> transplantation is confronted by the same immunologic barriers which threaten all grafts between genetically dissimilar partners. It is concluded that this experience supports the scientific feasibility of heart transplantation in man.

The first human heart transplant was performed on December 3, 1967 by Barnard in Capetown, South Africa (Barnard, 1967; Barnard and Pepper, 1969). Barnard, as described by Shumway (1981), had just returned to Capetown after a period of observing orthotopic heart transplants in the laboratory at the Medical College of Virginia, where Lower had gone to join Dr. David Hume (Shumway, 1981). As recorded by Barnard, this was only one of his many experiences that he felt resulted in his decision to perform his first clinical heart transplant (Barnard and Pepper, 1969:244). As he notes, there were other experiences he held dear:

> ...I applied for a training course under one of the great pioneers in this field--Dr. David Hume, formerly of Harvard and now with the Medical College of Virginia, at Richmond. Dr. Hume and his team were experienced both in kidney grafts and rejection control. He graciously accepted me for a three-month course, to begin in August.
>
> Since my first return from Minneapolis, I had made six trips abroad--attending conferences, seminars, and visiting medical centers in Europe, the Soviet Union, India, Australia, and New Zealand. Whenever possible, I also returned to America because it was there I learned the most.
>
> Richmond was no exception. It met with all my expectations. Dr. Hume assigned me to work in a renal transplant unit, and I assisted at kidney transplant operations. With this I learned how to manage these patients in the postoperative period. I studied rejection and its control by means of drugs in rats, dogs, and people. Besides this, Dr. Hume allowed me to visit other medical centers working on the same problem. This included Denver, where they had developed the use of antilymphocyte serum as an immunosuppressive agent.
>
> There was a spirit of open scientific inquiry at Richmond which was stimulating. The staff included Dr.

> Richard Lower who had worked with Dr. Norman Shumway on the technique of heart transplant. Prodded by Dr. Hume, we never slept and the drama never ceased.

On December 3, 1967, Barnard transplanted the heart of a 25 year-old woman into 55 year-old Louis W. Washkansky at Groote Schuur Hospital. Washkansky lived 18 days before succumbing to a combination of infection and rejection.

The first experience with clinical heart transplantation is recalled by Barnard as follows (Barnard and Pepper, 1969:290):

> On the way to the operating theatre, I felt for the first time that the transplant was actually going to happen. Until that moment, there had been so many hurdles to cross, that the reality of the event had been lost in getting ready for it. Only now did it seem possible. And only now, alone in the passage leading to this theatre, was I aware that I was walking forward with the hope that I would never get there, that something would still block my way.
>
> The further I went, the worse it became. With each step, the weight of my doubt grew until it seemed almost unbearable. I wanted to turn back, but there was no turning. Two people--a girl and a man--were now being moved into adjacent theaters. Both of them had living hearts that could not continue to beat for much longer. We were approaching the moment when there would be nothing else to do other than cut out both their hearts, and place one of them--the girl's--within an empty chest of this man who would otherwise never leave the operating table alive.
>
> If we succeeded it would be more than the grafting of a heart. It would be the conjoining of many disciplines of medicine and science. It would also be the crowning effort of a team of men and women who would bring to bear upon that moment the training of a lifetime, structured with the inherited technique and skill of a millennium. All of it would be fused into one objective--to replace a dying heart with a new one, to save one live.

While Barnard's autobiography reveals considerable uncertainty surrounding his first transplant, historical accounts frequently fail

to reflect this. Barnard asked himself the very same questions that many physicians do when faced with uncertainty verging on adversity. He recalls his thoughts on the day of surgery as follows (Barnard and Pepper, 1969:292-293):

> Your dogs didn't live long enough. You're not ready for this.
>
> This isn't a dog it's a man.
>
> That's just it. You haven't any right to experiment on a human being. It isn't a dog.
>
> I'm not experimenting. I know what I can do. We've proven we can transplant a heart and make it work.
>
> It'll work, will it? For how long?
>
> I don't know.
>
> You see what I mean? How can you go into such an undertaking if you don't have some idea of how long it'll work?
>
> That's not a fair question. How many times have others tried to cure a patient without knowing whether or not it'll work?
>
> But in treating a patient, we don't cut out his heart. We don't terminate his life. Whatever life is left, we leave to him. You're going to take life away from a man with the belief that you can sew it back. That is an enormous step. You'd better be damned sure you know what you're doing. Otherwise it will simply mean you've transformed two operating theatres into laboratories and substituted human beings for dogs.
>
> No, it's different. We use healthy dogs for experiments and they don't need a transplant. This is a dying man and something must be done. We must act. We must save his life if we have the means for it, and we have them, including a waiting donor and a waiting team.
>
> But for how long, Chris? How long will he live?
>
> Suppose I say a year, would you say it was worth it?
>
> Yes.
>
> And if it's only a month?
>
> I don't know.
>
> A week?
>
> Certainly not.
>
> How can you say that? Have you the right to decide how long a man can live?
>
> You're doing that man. You're going to cut out Washkansky's heart. That's a decision on how long someone can live--if ever there was one.
>
> No because he's not living. He's dying. He wants to live again. He wants his life extended. Suppose it is only a few days--but in those few days he can walk and see the sky and feel alive again. Do you have the

> right to say: 'No, Mr. Washkansky, you can't have those few precious days.' Who are you to hold back such a promise? How can the length of an added life be measured against its death? There is no way to measure the promise against the refusal.
>
> You should never have made the promise, until you were sure you could deliver.

Barnard recognized that performing this first procedure would commit him to do others. A failed transplant would signify defeat and would underscore the general belief that the procedure had been performed too early. He felt the need to continue until he was successful. And success he found with his second transplant.

On January 2, 1968, Barnard performed a second heart transplant on Capetown dentist Philip Blaiberg. Blaiberg lived nearly 18 months before dying. Blaiberg died of "...heart failure due to smoldering coronary artery insufficiency traceable in turn to chronic rejection. The autopsy did not show any of the ordinary changes in the heart muscle associated with acute rejection of the heart. Instead, there was marked narrowing and hardening of the coronary arteries, much more so than in the aorta and femoral arteries, the large arteries of the abdomen and the leg" (Moore, 1970:274). The development of coronary artery disease in heart transplant recipients is now a well-recognized problem (Baumgartner et al., 1979; Copeland and Stinson, 1979).

Moore (1972:263) notes that Barnard's first transplant added little to the general stock of knowledge concerning transplantation. What the operation did was to create a tremendous amount of publicity. He comments as follows:

> The most important impact of this operation was not in transplant science itself, but rather in worldwide attention to a medical event. The publicity was

> unequaled in two decades of biomedical science, rivaling news devoted to international politics, war, and the exploration of space, and bringing the field of transplantation into every home that had a television set, radio, or a newspaper.

Actually, the initial heart transplant stimulated a great deal of interest in cardiac transplantation worldwide. As shown in Table 3-1, there was a flurry of activity in 1968 with a precipitous decline by 1970, largely attributable to low survival rates (see Table 3-2). Looking back over this initial three-year period, of the 64 teams that had engaged in heart transplants, two teams (those of Shumway and Denton Cooley) had done more than 25 percent of the procedures. Fifty-four teams had done no more than one to three procedures: thirty-eight had done one cardiac transplant, thirteen had done two, and three teams had performed three. Together, these fifty-four teams accounted for seventy-three of the total of 167 transplants reported by the National Heart Institute as of December 1, 1970 (Fox and Swazey, 1974).

Fox and Swazey (1974) have thoroughly reviewed the events leading up to what they call the "heart transplant moratorium" that began in 1969 and was very evident by 1970. The death of the world's most celebrated heart transplant recipient, Dr. Philip Blaiberg on August 17, 1969, did not increase public or professional outcry for a moratorium. There was, nonetheless, a continued decline in the number of procedures performed worldwide. Only at Stanford, has the number of heart transplants performed continued to increase (see Table 3-3) over the years.

In a critical appraisal of the events surrounding and immediately following Barnard's first heart transplant, Shumway (1981) notes:

Table 3-1
Number of Heart Transplants By Month
(January 23, 1964 through December 31, 1970)

DATE	NUMBER OF TRANSPLANTS
December, 1967	2
January, 1968	4
February, 1968	1
March, 1968	0
April, 1968	1
May, 1968	12
June, 1968	4
July, 1968	7
August, 1968	8
September, 1968	17
October, 1968	17
November, 1968	26
December, 1968	6
January, 1969	8
February, 1969	5
March, 1969	4
April, 1969	11
May, 1969	3
June, 1969	3
July, 1969	5
August, 1969	2
September, 1969	3
October, 1969	1
November, 1969	0
December, 1969	1
January, 1970	4
February, 1970	1
March, 1970	0
April, 1970	2
May, 1970	4
June, 1970	0
July, 1970	0
August, 1970	2
September, 1970	0
October, 1970	2
November, 1970	0
December, 1970	0

SOURCE: Fox and Swazey, 1974.

Table 3-2
Heart Transplant Recipient Survival and Mortality
Through May 30, 1970 (N=162)

TIME (MONTHS)	PATIENTS ALIVE AS OF 5/30/70	PATIENTS DEAD AFTER SURVIVING TO INTERVAL
0-3	3	104
4-6	3	20
5-9	2	5
10-12	1	3
13-15	0	7
16-18	2	3
19-21	7	2

SOURCE: Reproduced from Fox and Swazey, 1974:138.

NOTE: The 162 patients include 3 retransplants and 1 artificial heart-human heart transplant, for a total of 166 operations.

Table 3-3
Number of Heart Transplants At Stanford By Year

YEAR	NUMBER OF PROCEDURES*
1968	10
1969	9
1970	8
1971	12
1972	14
1973	15
1974	15
1975	19
1976	21
1977	20
1978	31
1979	25
1980	22
1981	25
1982	28
1983	39

*Excludes heart-lung transplants.

> No experimental orthotopic heart graft had survived more than a few hours in South Africa when Barnard's initial clinical effort took the world by surprise. Suddenly heart transplants were being done in places where one would hesitate to have his atrial septal defect closed. Hardly a program could support its clinical activity with an experimental program, and high mortality soon had its effect on patient referral.

Historically, Shumway has been optimistic about the future of heart transplantation. Remarks such as the above are merely indicative of his concern that the procedure be performed at institutions that are equipped adequately.

Stanford has made much progress in making clinical transplantation a realistic alternative for selected patients with end-stage cardiac disease (Jamieson et al., 1984). A strong laboratory program continues to be the cornerstone of their activity. Survival of patients transplanted since 1974 now stands at about 80 percent at one year and 50 percent at five years. The developments contributing to these improvements have resulted from laboratory work. For example, Dr. Philip Oyer was responsible for developing rabbit antithymocyte globulin. Dr. Charles Bieber has improved upon this immunosuppressive agent making it safe for intravenous administration (Bieber et al., 1976; 1977; 1981). Another advance, fully developed in the laboratory by the late Dr. Philip Caves, was the transvenous intermyocardial biopsy (Caves et al., 1973a; 1973b; 1973c; 1974a; 1974b). Caves redesigned the original cardiac biotome of Sakakibara and Konno (1962) so that it could be passed into the apex of the right ventricle percutaneously via the internal jugular vein in humans and via the external jugular vein in dogs. The biotome remains one of the most

significant developments in heart transplantation. It is a very reliable tool used in the detection of rejection.

In summary, since the initial clinical heart transplantation in 1967, remarkable achievements have been made in the field of organ transplantation. Perhaps the only major setback has been the relatively slow pace of the progress. Both infection and rejection remain very significant problems, while the development of "transplant disease" is a major problem confronting transplant physicians. Dr. William Pfaff (University of Florida), uses this terminology to describe the host of problems that beset the long-term survivors of various organ transplants. These problems include bone disease, cancer, hirsutism, and other disorders attributable to chronic immunosuppression.

B. THE CURRENT STATUS OF CLINICAL HEART TRANSPLANTATION

It could be said that clinical heart transplantation has come of age. Patient survival rates have now improved to a point where they parallel cadaveric kidney transplant patient survival rates. Moreover, based on the nature of heart transplantation where patient and graft survival rates are really one in the same, except in instances where a retransplantation has been possible, the more appropriate comparison would be heart transplant patient with kidney transplant graft survival rates. Kidney transplant patient survival rates do not provide a fair comparison because these patients have the option of return to kidney dialysis once graft failure has occurred.

Based on published data from the Stanford group (Pennock et al., 1982) and Krakauer (1980), Figures 3-1 and 3-2 show the comparisons

FIGURE 3—1

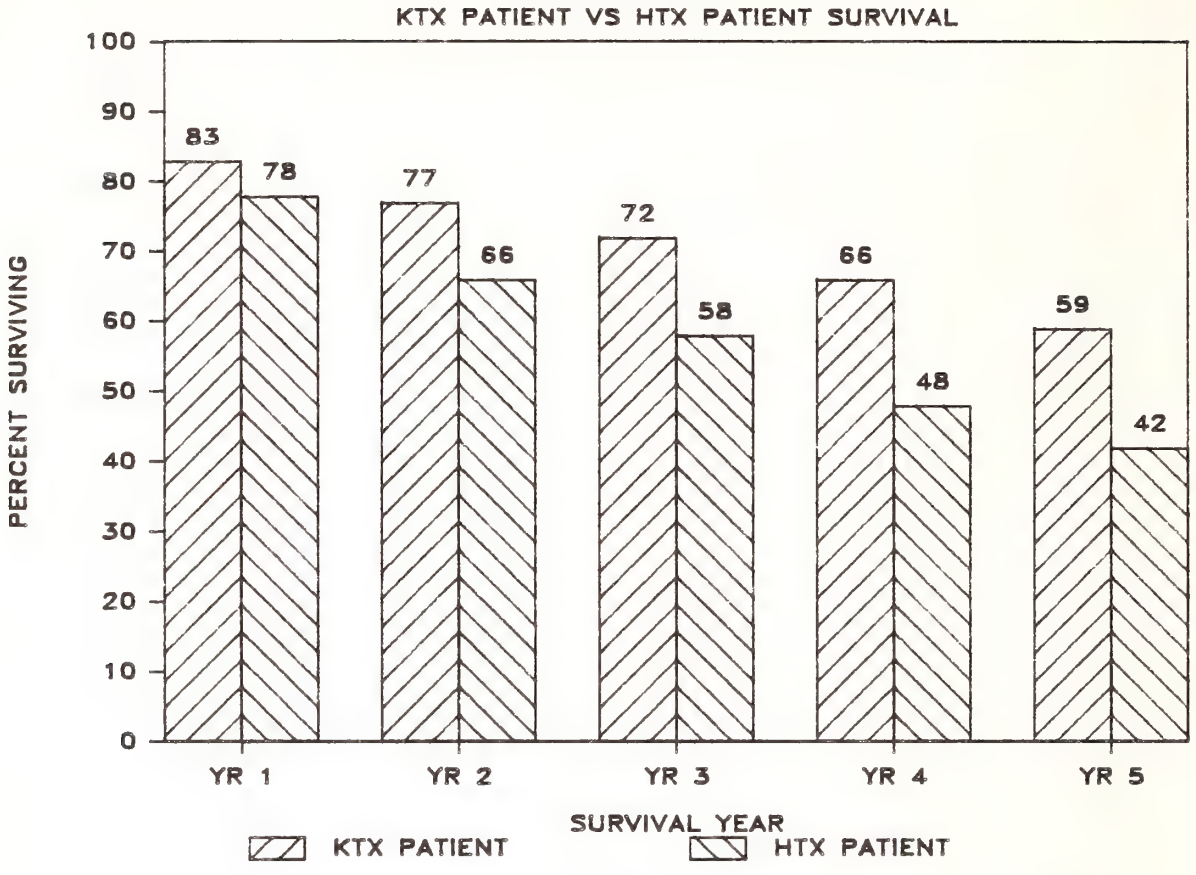
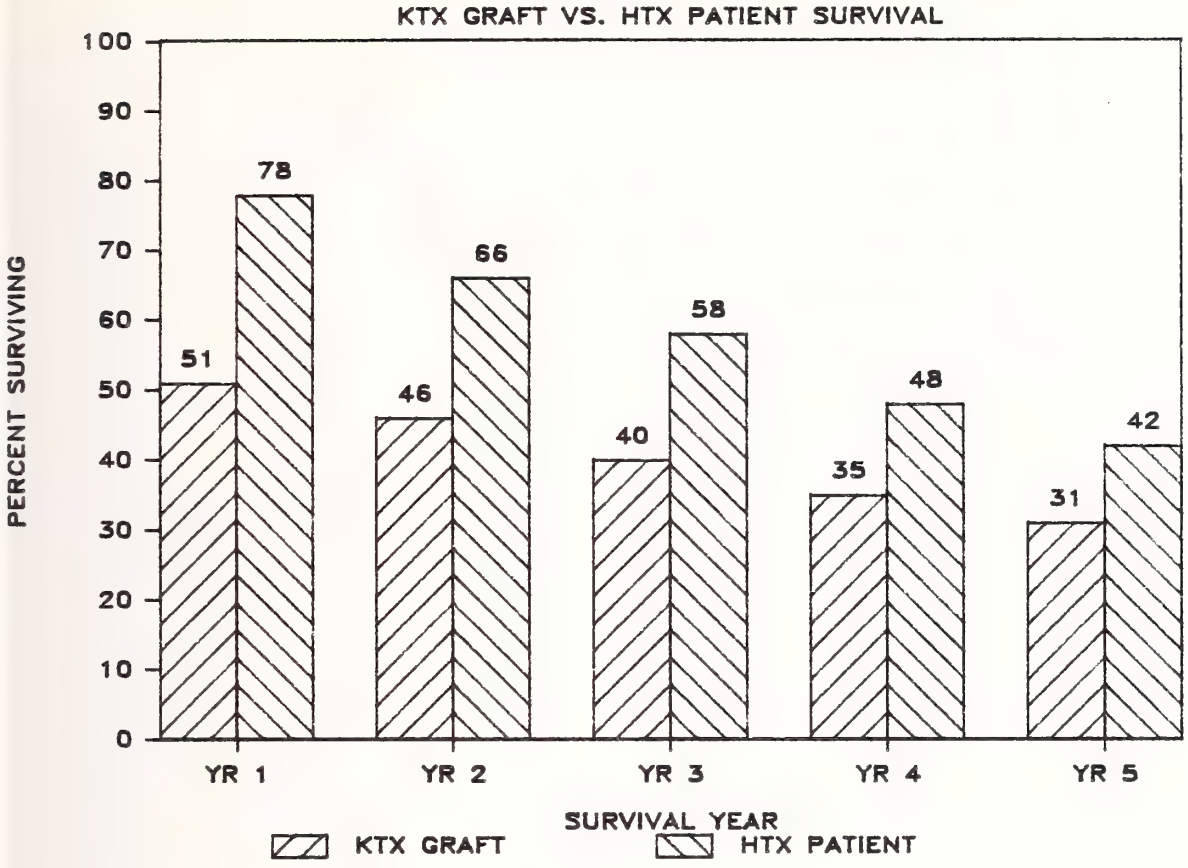

KTX PATIENT VS HTX PATIENT SURVIVAL
PERCENT SURVIVING
100
90
80
70
60
50
40
30
20
10
0
83
78
77
66
72
58
66
48
59
42
YR 1
YR 2
YR 3
YR 4
YR 5
SURVIVAL YEAR
KTX PATIENT
HTX PATIENT

FIGURE 3-2


KTX GRAFT VS. HTX PATIENT SURVIVAL
PERCENT SURVIVING
100
90
80
70
60
50
40
30
20
10
0
51
78
46
66
40
58
35
48
31
42
YR 1
YR 2
YR 3
YR 4
YR 5
SURVIVAL YEAR
KTX GRAFT
HTX PATIENT

described above. Figure 3-1 is a comparison of cadaveric kidney transplant patient with heart transplant patient survival. Figure 3-2 is a comparison of cadaveric kidney transplant graft survival and heart transplant patient survival. Based on the latter more realistic comparison, it is evident that heart transplant recipient survival clearly exceeds that of kidney transplant recipient graft survival for one through five years (Evans, 1984).

Differences in kidney transplant graft and heart transplant patient survival rates are at least due, in part, to differences in patient selection criteria. As noted above, over time, there has been a tendency to relax selection criteria for kidney transplant recipients. As of yet, the same has not been true of heart transplant patients. The criteria used to select heart transplant recipients remain very restrictive (Pennock et al., 1982; Baumgartner et al., 1979; Copeland and Stinson, 1979; Lower et al., 1979). As selection criteria are relaxed, however, it will not be surprising to find patient and graft survival rates decline.

As discussed above, the first heart transplant in the United States was performed in 1967. Table 3-4 shows the number of heart transplants performed each year in the U.S. The marked increase since 1980 roughly coincides with the introduction and use of cyclosporine in heart transplant recipients. The Stanford group initiated their cyclosporine trials in December, 1980 (Oyer et al., 1983:2546). The University of Pittsburgh began its trial in March, 1981 (Hardesty et al., 1983:2553). By March, 1983 nearly all active heart transplant programs in the U.S. were using cyclosporine.

Table 3-4
Number of Heart Transplants Performed By Year, U.S.

YEAR	NUMBER OF PROCEDURES PERFORMED
1967	1
1968	54
1969	34
1970	16
1971	13
1972	14
1973	19
1974	21
1975	23
1976	24
1977	23
1978	34
1979	32
1980	36
1981	62
1982	103
1983	172
TOTAL	681

There are currently about 25 heart transplant programs in the U.S. In 1983, 13 of these programs, including McGuire VA Hospital in Richmond, Virginia, performed 172 heart transplants and 13 heart-lung transplants (see Table 3-5). In 1984, the Brigham and Women's Hospital (Boston), Temple University (Philadelphia), Yale University (New Haven), and Loyola University (Maywood), Baylor College of Medicine (Houston), UCLA Medical Center (Los Angeles), University of Michigan (Ann Arbor), University of Wisconsin (Madison), VA Hospital (Buffalo), Pacific Medical Center (San Francisco), and St. Joseph's Hospital (Phoenix), all announced that they were initiating heart transplant programs or performed one or more heart transplants. It is likely that over the next year many other hospitals will initiate heart transplant activities. Thus far few private institutions have initiated programs (Haag et al., 1983), although the number is increasing. The staff at Methodist Hospital has argued that it is reasonable for private institutions to become involved because the procedures can be performed at a cost substantially below that of university medical centers.

There are many more people who could potentially benefit from heart transplantation than have or may ever receive them (see Chapters 10-14). Estimates have been as high as 75,000 (Schroeder, 1979) and as low as 1,000 (Pennock et al., 1982). Nonetheless, there are several constraints on the overall level of transplant activity at this time. They are: (1) cost and reimbursement, (2) number of centers performing them, and (3) the acute shortage of donor organs. In principle, the first two constraints could be eliminated. The latter, however, cannot. The supply of donor organs is finite (see Chapters 15-19).

Table 3-5
Number of Heart Transplant Procedures By Institution, 1983

INSTITUTION	NUMBER OF HEART TRANSPLANTS	NUMBER OF HEART-LUNG TRANSPLANTS
Stanford University Medical Center*	39	7
University of Pittsburgh*	29	5
Medical College of Virginia (and VA)*	20	
Columbia-Presbyterian Hospital*	26	
Texas Heart Institute	16	
University of Minnesota*	14	
University of Alabama	11	
University of Arizona*	10	
Methodist Hospital (Indianapolis)	7	
St. Louis University Hospital	6	
Johns Hopkins	4	1
Mayo Clinic	0	—
TOTALS	172	13

*Participating in the National Heart Transplantation Study

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CHAPTER 4

IMMUNOSUPPRESSIVE AGENTS AND TECHNIQUES: THE ACHILLES' HEEL OF ORGAN TRANSPLANTATION

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A. INTRODUCTION

Progress in organ transplantation has been closely linked with developments in the identification and development of immunosuppressive agents and techniques. Historically the most significant of setbacks have been related to immunosuppression, particularly rejection. To avoid this unfavorable outcome of transplantation, two approaches have been followed. The first has been to minimize the risk of rejection through the identification of a histocompatible donor for the transplant recipient. The second approach has entailed the refinement of immunosuppressive agents and techniques. Limitations associated with each of these approaches have been the Achilles' Heel of transplantation.

The primary objectives of this chapter are to review the historical development of immunosuppression, critically appraise the results of cyclosporine in kidney transplantation, and review the results of cyclosporine in heart transplantation. A considerable amount of data is presented in this chapter based upon published reports.

The history of developments in immunosuppression has been reviewed by Bach (1979) and Calne (1981). This history is worthy of consideration here since it provides a clear indication of progress made thus far. Although progress is perhaps best characterized as slow, it has, nonetheless, been steady. Over the past year, considerable attention has focused on cyclosporine, the most recent immunosuppressive agent approved by the Food and Drug Administration for use in transplant recipients.

Several reports have heralded cyclosporine as a "miracle" drug (Kolata, 1983; Macek, 1983), although it is clear the drug is no

panacea. Immunologist, Jean F. Borel (Borel et al., 1976; 1977; Borel, 1982; White, 1982) of Sandoz Ltd. (Basel, Switzerland), who discovered the agent's immunosuppressive properties in 1972, has noted that: "It must be pointed out that cyclosporine is no panacea. It has nevertheless been shown to be the most potent and specific immunosuppressant so far discovered and to have an acceptable incidence of side effects." Just how acceptable these side-effects are, however, remains a subject of debate (Anonymous, 1983; Blagg and Evans, 1983).

B. CHEMICAL IMMUNOSUPPRESSION EXCLUDING CYCLOSPORINE

Chemical immunosuppressive agents are synthetic products that have one of two functions, to suppress or depress immune responses. In 1958, Schwartz and co-workers (1959) demonstrated that 6-mercaptopurine (6-MP) could prevent production of antibodies against bovine serum albumin. Since then many other agents have been found to have immunosuppressive properties but 6-MP (Purinethol) and its imidazole derivative azathioprine (Imuran) are still the most used immunosuppressive agents in human transplantation (Bach, 1981).

Azathioprine was first synthesized in 1961 by Elion and associates (1961), eleven years after they synthesized 6-mercaptopurine (Elion et al., 1952). In vitro, azathioprine inhibits most activities of human lymphocytes. Under certain conditions it also has an anti-inflammatory action (Bach, 1981).

The major complications of azathioprine therapy include: (1) infections and viral complications, (2) hepatitis, (3) bone marrow aplasia, and (4) malignant diseases. Unlike other immunosuppressive agents, azathioprine may result in the development of malignant

tumors. Penn (1979) has reported that the incidence of tumors is approximately 100 times greater than in the general population controlling for age (Penn, 1982; 1983).

Corticosteroids have also been shown to have immunosuppressive properties. In 1950, Germuth and Ottinger (1950) first demonstrated that cortisone was an immunosuppressant. In 1951, Bellingham et al. (1951) showed that high doses of cortisone would prolong skin allograft survival, but the prolongation was slight. Similar results were observed with other organ allografts (Zukowski et al., 1963). It was soon determined that corticosteroids were best used in conjunction with other corticosteroids (Bach, 1981), in particular the thiopurines (Marchioro et al., 1964), nitrogen mustards (Baker et al., 1952), and antilymphocyte sera (Hoelm and Simmons, 1967).

There are side effects associated with the use of steroids and these are the same as those observed in other situations where the drug is used. These complications are often serious. Steroids may encourage microbial and viral infections. They may cause gastrointestinal hemorrhage and perforation of gastric ulcers, severe diabetes and bone disorders, especially bilateral asceptic necrosis of the femoral head, which may be crippling (Bach, 1981). Serious psychological disorders may develop and persist following withdrawal of therapy. Bach (1981:104) concludes that "...steroid therapy represents one of the most serious hazards of kidney transplantion."

Cyclophosphamide (Endoxan, Cytoxan) is a alkylating agent. Although a powerful immunosuppressant in mice, it met with only a certain measure of success in man (Fox, 1964). In fact, the number of cases treated is too small to draw firm conclusions. When azathioprine

is poorly tolerated, especially because of bone marrow depression, cyclophosphamide may be substituted advantageously.

Additional drugs have been found to have immunosuppressive properties, but none are commonly used in man. The search continues for a drug that is a specific rather than general immunosuppressant that has minimal side-effects associated with its use.

C. ANTILYMPHOCYTE SERA

Metchnikoff (1899) made the first antileukocyte serum by injecting extracts of rat and rabbit lymph nodes and spleen into guinea pigs. But it was not until 1955 that the immunodepressive effect of ALS was discovered. Earlier, in 1951, Woodruff and associates (1951) had suggested that antilymphocyte sera might be helpful in transplantation. In 1961, Waksman et al. (1961) were able to achieve a slight increase in the survival of skin grafts in guinea pigs, but it was not until 1963 that Woodruff and Anderson (1963) achieved the first really long survival.

Over the years, a great deal of work has been done on ALS (Bach, 1974; Barna, 1977; James, 1967; Medawar, 1968). This work is far to vast to review here. (see Novick, 1983)

Recently preliminary research has revealed that monoclonal antibodies may hold immunosuppressive promise in organ transplantation. The hope is to identify a therapeutically predictable antilymphocyte in the form of a monoclonal antibody to T-lymphocytes or even a subpopulation (Cosimi, 1983). These developments are exciting. The initial experience of Cosimi and coworkers (1981) with the use of OKT3, a pan-T antibody was moderately encouraging (Morris, 1983).

There are clear indications that the intravenous administration of OKT3 eliminates circulating T-lymphocytes within minutes, but often after several days T-lymphocytes expressing the T4 or the T8 determinants but not T3 begin to reappear.

Morris (1983) notes that caution is required at this time. Despite the fact that he feels there is some promise, he suggests that the pan-T approach is "...perhaps best delayed until we know which lymphocyte subpopulation is the trigger for the rejection reaction!"

Like all immunosuppressive agents, antilymphocyte sera are not without side-effects. First, it is painful and produces an inflammatory reaction at the site of injection (Kashiwagi et al., 1968; Traeger et al., 1969). Second, in man some sera provoke thrombocytopenia (Bach, 1981) and others produce thrombocytosis, while still others have no appreciable effect on the number and functions of platelets. These findings depend on both the nature and dosage of ALS. Third, in man, sensitization to horse protein is common. Bach (1981) notes that this may lead to several complications such as urticaria, malaise with hypotension, sometimes major anaphylactic shock with collapse and respiratory embarrassment and, occasionally serum sickness. Fourth, ALS may be nephrotoxic although thus far there is little evidence of this. Finally, in man, ALS, like azathioprine, may facilitate the development of malignant tumors. Since many transplant recipients receive multiple drugs it is difficult to determine which of the several drugs have a primary role in tumor development.

D. OTHER NONSPECIFIC IMMUNOSUPPRESSIVE TECHNIQUES

Total body irradiation temporarily depresses immune responses. In 1950, Dempster et al. (1950) first suggested that this technique be applied to transplantation. In man, total body irradiation was the first method of immunosuppression used in kidney transplantation. It was used at Necker Hospital in 32 patients between 1959 and 1963 (Bach, 1981). Unfortunately, a significant number of cases of septicemia developed. For this reason, total body irradiation was rejected in favor of clinical immunosuppression.

Total lymphoid irradiation (TLI) is a technique commonly applied in the treatment of Hodgkins disease and non-Hodgkins' lymphomas (Strober et al., 1979). This form of treatment has shown profound immunosuppression that was selective for T-cells (Sutherland et al., 1983e). TLI appears to be one of the most potent methods of preventing allograft rejection and inducing tolerance to alloantigens in adult animals (Slavin et al., 1978; 1979; Strober et al., 1979; Zan-Bar et al., 1978). This technique has been occasionally applied by the Stanford heart transplant team (Modry et al., 1983; Sadeghi et al., 1983). The University of Minnesota has also used it in conjunction with cyclosporine (Sutherland et al., 1983d).

Irradiation of the blood has been suggested by Cronkite and associates (Chanana et al., 1969) has a potentially useful technique. It has only been applied in animals thus far.

Irradiation of the kidney allograft has been recommended as a useful technique for the treatment of crises (Kauffman et al., 1965). Bach (1981) indicates that they have been unwilling to use this technique because of the possibility of radiation damage to the kidney.

Thoracic duct drainage is another technique that has attracted considerable attention over the years. Tilney and Murray (1967) have been advocates of this technique. In France, Revillard (1970) has exhibited similar enthusiasm. Periodically there is renewed attention given to the merits of this technique (Bell et al., 1983; Niblack and Richie, 1983). Bach (1981) concludes that "...it is difficult to judge the effect of this procedure on allograft tolerance. At best, it can only be an auxiliary method."

Starzl (1964) was among the first to suggest that thymectomy may be of some utility in kidney transplantation. In 1970, Starzl et al. (1970) reviewed 24 patients who received a thymectomy at the time of transplant and found no improvement in patient survival, in dosage of immunosuppressive drugs required, or in renal function compared with a control group. Bach (1981) states that he knows of no one currently using these techniques for purposes of immunosuppression.

The literature in the past has suggested that splenectomy is a useful technique with immunosuppressive implications (Krohn, 1953). Ungar indicated that by reducing the mass of lymphoid tissue, grafts may be tolerated better with a reduced possibility of rejection (Krohn, 1953; Kountz and Cohn, 1962). Bach (1981) concludes that there is little evidence that routine splenectomies improve graft survival by making immunosuppressive drugs more effective. At least one major transplant program in the U.S.--the University of Minnesota--continues to splenectomize patients as part of their standard transplant protocol (Najarian et al., 1983b). Patients who receive conventional therapy as well as those placed on cyclosporine are splenectomized.

Although not an immunosuppressive technique per se, blood transfusions prior to kidney transplantation have been demonstrated to prolong graft survival (Salvatierra et al., 1983b). Dialysis patients who have received blood transfusions and later were transplanted have better graft survival rates than patients not given transfusions (Morris, 1983). In fact, Terasaki and coworkers (1983) who were the first to report on the beneficial effects of blood transfusions have recently reconsidered the impact of pretransplant blood transfusions on graft survival rates. They note that graft survival rates showed a steady decline from 1968 to 1975 but subsequently improved at a rate of 2.4 percent per year for parent donor transplants and 2.7 percent per year for cadaver donor transplants. During this period of improving survival rates, the pretransplant transfusion exposure rate increased from 52.0 percent in 1977 to 91.0 percent by 1981. This led Terasaki and coworkers (1983) to conclude that "...transplantation has now reached a new level of acceptability as a clinical treatment modality and that blood transfusion has produced its effect on graft survival when results are disseminated over a large number of transplant centers."

Blood transfusions have been both donor and non-donor specific. The results reviewed above are largely characteristic of non-donor specific transfusions. The results of donor-specific transfusions are actually more remarkable, and are also worthy of consideration (Mendez et al., 1984).

In 1978, Salvatierra and coworkers first introduced pretransplant donor-specific blood transfusions (DST) in "...an attempt to select potentially successful transplants from among immunologically

disparate related donor-recipient pairs" (Salvatierra et al., 1983a; 1983b). Early results were very positive and subsequent results from a larger experience with DST has demonstrated the efficacy of this procedure at the University of California, San Francisco as well as other centers which have adopted this protocol (Yamauchi et al., 1983; Sollinger et al., 1983; Ettenger et al., 1983). The only truly significant problem associated with DST has been an "...unfavorable degree of sensitization," currently estimated to be about 30.0 percent. Light and coworkers (1983) have reported on one approach to eliminate the risk of sensitization--drawing one donor unit, dividing it into 3 aliquots, and administering transfusions as 1/3 unit as 1, 3, and 5 weeks following blood donation.

Recently, the use of cyclosporine has called into question the efficacy of blood transfusions (Niessen et al., 1984), despite the fact that the European Multicentre Trial Group's (1983) comparison of cyclosporine with azathioprine and prednisolone in renal transplantation found that non-transfused patients had a better graft survival than did multiply transfused patients in the cyclosporine group. In the dog model Niessen and coworkers (1984) have concluded that: "During the cyclosporine period no difference in graft survival was observed between transfused and non-transfused littermates." Yet, in concluding their analysis, Niessen et al. (1984) recommended that: "It might be rewarding to transfuse patients just in case conversion, temporary or otherwise, from cyclosporine to conventional immunosuppression proves necessary..."

The foregoing is a brief summary of the development and use of selected immunosuppressive drugs and techniques. Because of the

enthusiasm which currently surrounds cyclosporine, it is more carefully scrutinized in the review that follows. Within the general scheme presented above, cyclosporine would be properly classified as chemical immunosuppression along with other major drugs such as prednisone and azathioprine.

E. CYCLOSPORINE AS AN IMMUNOSUPPRESSIVE AGENT

The immunosuppressive properties of cyclosporine were described by Borel in 1976 (Borel, 1976; Borel et al., 1983; Morris, 1981; White, 1982; Flechner, 1983). Cyclosporine-A, as the drug was then referred to, is a cyclic peptide (11 amino acids) which was initially used as an antifungal agent. Borel and Schwartz (1964) via routine screening, noticed that cyclosporine-A exerted a variety of immunosuppressive responses in rodents and guinea pigs. Gradually, studies in animals and man have confirmed the immunosuppressive properties of cyclosporine. A review of the history of cyclosporine, adapted from Borel (1983), is provided in Table 4-1.

The first clinical trials of cyclosporine began in 1978. These trials involved the use of cyclosporine in the treatment of graft-versus-host disease (GVHD) and also in renal transplantation (Beveridge, 1983). Since then, the primary use of cyclosporine has been as prophylaxis (as opposed to treatment) in bone marrow transplantation for GVHD. This is likely to change very rapidly in the near future.

Several major clinical trials of cyclosporine have been completed or underway. In fact, it is estimated that cyclosporine is being clinically tested in more than 100 centers in 19 countries. Over 1600

Table 4-1
Review of the History of Cyclosporine

DATE	KEY PERSON(S)	EVENT
1970	B. Thiele	Isolation of new strains of fungi impeficti producing antifungal metabolites.
1970	Z.L. Kis et al.	Isolation of a metabolite mixture and characterization as novel neutral polypeptides.
1971	Haerri/Ruegger	Isolation of the partially purified two component metabolite mixture (24-556) on a preparative scale for initial biologic screening.
1972	Borel	Discovery of immunosuppressive properties of metabolite 24-556 in rodents.
1973	Ruegger	Purification of CsA (27-400).
1973	Dreyfuss et al.	Culture and production of CsA.
1974	Borel et al.	Animal studies of the immuno-suppressive activity of CsA, in vivo and in vitro.
1975	Petcher et al. Ruegger et al.	Elucidation of the structure of CsA (X-ray studies and chemical degradation).
1976	--	Toxicity studies (rats, monkeys) demonstrate selectivity of CsA for lymphocytes and lack of effect of hemopoiesis.
1976	--	Worldwide confirmation of specific immunosuppressive effect of CsA in experimental transplantations and other models.
1978	Calne et al. Powles et al.	First clinical trials (kidney transplantation, graft versus host disease).

Table 4-1 (Continued)
Review of the History of Cyclosporine

DATE	KEY PERSON(S)	EVENT
1980	Wenger	Total synthesis of CsA (Ruzicka Award presented in 1982).
1981	Bueding et al. Thommen	Publication of antischistosomal and and antimalarial activity of CsA. CsA symposium at Trinity Hall, Cambridge.
1983	---	Sandimmune first registered in Switzerland.
1983	---	First International Congress on Cyclosporine, Houston, Texas.
1983	---	Approval of cyclosporine by the U.S. Food and Drug Administration

Adapted from Borel, 1983:2222.

patients have received the drug (Beveridge, 1983). Results from many of the larger clinical trials have been published, several in the past twelve months. Results from the European Multicentre Trial (1982; 1983) have been published as well as those from the Canadian Multicentre Study Group (1983; Stiller et al., 1983). In addition, results from trials at single institutions have also been published, among them the University of Minnesota, the University of Pittsburgh, and the University of Cambridge.

Cyclosporine is now used for human kidney, liver, heart, heart-lung, bone marrow, pancreas, and lung transplants (Starzl et al., 1980; European Multicentre Trial, 1982; 1983; Starzl et al., 1983; Hakala et al., 1983; Najarian et al., 1983a; 1983b; Ferguson et al., 1982; Kahan et al., 1983; Stiller et al., 1983; Starzl et al., 1981; Starzl et al., 1983; Zitelli et al., 1983; Wonigeit et al., 1983; Oyer et al., 1983a; 1983b; Hardesty et al., 1983; Wallwork et al., 1983; Cooley et al., 1983; Reitz et al., 1982; Powles et al., 1980; 1983; Tutschka et al., 1983; Speck et al., 1983; Storb et al., 1983; Sutherland, 1983; Sutherland et al., 1983a; 1983b; Traeger et al., 1983; Kamholz et al., 1983; Jamieson et al., 1983; 1984; Reitz, 1982; Traeger et al., 1983; Sutherland et al., 1983c). In the U.S., on November 14, 1983, cyclosporine was approved by the Food and Drug Administration, prompting more widespread usage, primarily by renal transplant teams. Without question the greatest usage of and experience gained with cyclosporine has been by renal transplant teams.

In what follows, a comparative review has been undertaken of the results of the major clinical trials of cyclosporine by renal transplant teams. The published reports have been reviewed with

respect to the following: (1) drug protocols, (2) patient and graft survival, (3) infection and rejection, and (4) side-effects and toxicity. Following this review, attention is then directed to the trials of cyclsporine currently underway at two major heart transplant centers.

1. CYCLOSPORINE AND KIDNEY TRANSPLANTATION

Even a cursory review of the major trials of cyclosporine in renal transplantation produces a startling conclusion: the study results are very inconsistent (Evans, 1984). Table 4-2 summarizes the nature of the inconsistencies. The text which follows elaborates upon them in detail and suggests possible reasons why the study results are inconsistent. Finally, the sparse data on the comparative cost-effectiveness of cyclosporine with conventional therapy is reviewed (Ferguson, 1983).

At the outset it should be recognized that few of the published studies on cyclosporine are truly controlled clinical trials, most are uncontrolled trials with historical controls. This means that comparisons between immunosuppressive drug regimens are not as precise as would be desirable. For example, both the Canadian Trial and the European Trial permitted each participating center to use the "best available local therapy" as the conventional therapy. Thus, conventional therapy frequently consists of more than just azathioprine and prednisone. Also, some studies, such as those at the University of Minnesota and the University of Pittsburgh, as well as the Canadian Trial, supplement cyclosporine with prednisone. Only the European Trial uses cyclosporine as the sole immunosuppressive agent. The trend, however, is to use cyclosporine

Table 4-2
Summary of Findings of Five Separate Clinical Trials Comparing Cyclosporine with Conventional Immunosuppressive Therapy

	DRUG PROTOCOL		PATIENT SURVIVAL	GRAFT SURVIVAL	INFECTIONS	REJECTIONS
REFERENCE TO CLINICAL TRIAL	CONVENTIONAL THERAPY	CYCLOSPORINE	HIGHER ON CYCLOSPORINE?	HIGHER ON CYCLOSPORINE?	LOWER ON CYCLOSPORINE?	LOWER ON CYCLOSPORINE?
UNIVERSITY OF[1] CAMBRIDGE	Azathioprine Prednisone	Cyclosporine Only	No	No	NR**	No
CANADIAN TRIAL[2]	"Best Available Local Therapy"	Cyclosporine and Prednisone	No	Yes*	No	No
EUROPEAN TRIAL[3]	"Own Best Conventional Protocol"	Cyclosporine Only	No	Yes	No	NR
UNIVERSITY OF[4] MINNESOTA	Antilymphocyte globulin (ALG) Azathioprine Prednisone	Cyclosporine and Prednisone	No	No	Yes	Yes
UNIVERSITY OF[5] PITTSBURGH	Azathioprine Prednisone	Cyclosporine and Prednisone	No	Yes	Yes	NR

*YES = Difference is statistically significant.

**NR = Not Reported in literature cited in the text.

[1]Merion et al., 1984

[2]Canadian Multicentre Transplant Study Group, 1983

[3]European Multicentre Trial Group, 1983

[4]Najarian et al., 1983a

[5]Hakala et al., 1983

and low dose prednisone. If a true randomized clinical trial were undertaken today, it would compare conventional therapy consisting of azathioprine and prednisone with cyclosporine supplemented with low dose prednisone. Unfortunately, none of the multicenter clinical trials completed as of this date make such a comparison.

Many of the clinical trials of cyclosporine are further complicated by drug switching. Patients who do not fare well on cyclosporine have been, in most cases, permitted to switch to conventional therapy. In the Canadian Trial, for example, 12 cyclosporine-treated patients were switched to standard therapy between 2 days and 15 months after transplantation. In the European Trial, 24 of the 84 patients in the cyclosporine group with functioning grafts at one year were switched to conventional therapy. In the Cambridge study, of the 79 patients initially given cyclosporine, 12 (15.2%) were switched to conventional therapy from four days to 34 months after transplantation (Merion et al., 1984). In only one of the studies reviewed here have patients been permitted to go from conventional therapy to cyclosporine, due to the numerous side-effects associated with the long-term use of steroids, particularly osteoporosis. In the Cambridge study, three (10.3%) of the 29 patients initially treated with azathioprine and steroids were switched to cyclosporine three to eight weeks after the grafting (Merion et al., 1984).

In conclusion, there are numerous reasons why the results of already completed clinical trials on cyclosporine must be viewed with caution. Few of these trials, with the exception of the Minnesota

trial, would actually meet the very stringent requirements of a true clinical trial where multiple "pure" treatments are compared (Lavori et al., 1983; Sacks et al., 1982). Unfortunately, in the clinical trials of cyclosporine to date, there has been too little emphasis on the purity of the treatment protocols being compared. Thus, it is not surprising that the results of many of the trials reviewed below, when compared, are inconsistent and inconclusive. Great care is required in future studies to correct for the deficiencies in the trials already completed.

a. Drug Protocols. Drug protocols currently followed by the major transplant programs vary considerably. Most protocols for conventional therapy include azathioprine and prednisone, but these drugs are often supplemented with other immunosuppressive drugs or techniques including antilymphocyte globulin (ALG) and total lymphoid irradiation (TLI) or, in some instances, thoracic duct drainage (TDD) (Bell et al., 1983; Niblack and Ritchie, 1983). The Minnesota protocols have been described at length elsewhere (Ferguson et al., 1982). Generally, conventional therapy at Minnesota includes a 14-day course of 30 mg/kg/day of ALG combined with a tapering azathioprine and prednisone schedule (see Table 4-3).

The cyclosporine protocol at Minnesota includes the oral administration of 14 mg/kg of cyclosporine prior to surgery. The patient is continued at this dose daily for one week posttransplant when it is decreased to a maintenance level of 12 mg/kg. The daily cyclosporine dose is then titrated to renal function as determined by the serum creatinine level. Prednisone is begun at 2 mg/kg and tapered to 0.3 mg/kg by three weeks posttransplant (see Table 4-4).

Table 4-3
Conventional Immunosuppression at the University of Minnesota

The standard immunosuppression protocol at the University of Minnesota includes antilymphoblast globulin given in a dose of 30 mg/kg/day intraveneously for 14 doses beginning the day after transplantation. Azathioprine therapy is begun the day before transplantation in a dose of 5 mg/kg and continued at this dose for the first 3 posttransplant days. Azathioprine administration is then tapered by .05 mg/kg/day increments at 3-day intervals until a maintenance of 2.5 mg/kg/day is reached. Prednisone therapy is begun the day after transplantation in a dose of 2 mg/kg/day. Prednisone administration is then tapered at 0.25 mg/kg/day. This dose is then maintained to posttransplant day 90 and gradually tapered to 0.25 mg/kg/day by 1 year. In addition, 1 gm methlprednisolone/day is given intravenously for the first 3 posttransplant days.

SOURCE: Ferguson RM, et al., 1982.

Table 4-4
Cyclosporine Protocol at the University of Minnesota

Cyclosporine is administered orally before the transplant in a dose of 14 mg/kg the day prior to transplantation. With cadaveric transplants this operative dose is given 6 to 8 hours before treatment. Cyclosporine is maintained at an oral dose of 14 mg/kg/day for the first posttransplant week, at which time it is decreased to 12 mg/kg/day and maintained at this level. After the first posttransplant month, the daily cyclosporine dose is titrated to nephrotoxicity as reflected in the serum creatinine.

SOURCE: Ferguson RM, et al., 1982.

The Pittsburgh group follows a somewhat different protocol for both conventional and cyclosporine-treated patients. Their protocol has also been described elsewhere (Hakala et al., 1983).

The Canadian Trial, as already noted, permitted great variation among participating centers in terms of conventional therapy but the protocol for cyclosporine was standard across centers (Canadian Multicentre Transplant Study Group, 1983). A loading dose of 20 mg of cyclosporine per kilogram of body weight was administered orally within 12 hours before surgery, and thereafter the patients received 10 mg per kilogram every 12 hours. Trough cyclosporine levels (in serum obtained 11 hours after the last dose) were determined by radioimmunoassay, and the oral dose was adjusted to achieve trough levels between 100 and 400 ng per milliliter. After 30 days, the dose was reduced by 2 mg/kg if trough levels were above 100 ng per milliliter. It was then reduced monthly, provided that the patients were clinically and immunologically "quiescent" and that the trough level was not less than 100 ng per milliliter.

On Day 14 the patients were started on prednisone, 1 mg/kg administered, on alternate days; if clinical conditions allowed, this dose was reduced by 5 mg every other day, to 0.3 mg given on alternate days. This dosage was maintained for three months, and then lowered to 0.25 mg per kilogram if there was no evidence of graft rejection. At six months, the prednisone dose was further reduced to 12.5 mg every other day.

The Cambridge group used standard protocols for both conventional therapy and cyclosporine throughout their trials. These protocols are described in Tables 4-5 and 4-6.

Table 4-5
Conventional Immunosuppression at
the University of Cambridge

Conventionally immunosuppressed patients received 2 mg of azathioprine per kilogram per day, tapered to 1.5 mg per kilogram per day over three weeks, with adjustments for leukopenia. Steroids were administered at 500 mg of intravenous methylprednisolone perioperatively, after which oral prednisolone was given at a dose of 0.5 mg per kilogram per day or its intravenous equivalent was given until oral intake was resumed. The steroid dose was tapered to 0.25 mg per kilogram per day over three weeks. Rejection episodes were treated with increased steroid doses. Steroid tapering was adjusted after antirejection therapy. Antilymphocyte globulin was not used.

SOURCE: Merion RM, et al., 1984.

Table 4-6
Cyclosporine Protocol at the
University of Cambridge

Patients placed on cyclosporine were given the initial doses intraveneously (4 mg per kilogram of body weight per day) until oral intake was resumed, usually on the first or second day after grafting. The initial oral dose of cyclosporine was 17 mg per kilogram per day. This was gradually tapered to 8 to 10 mg per kilogram per day during a period of six to eight weeks after discharge. Rejection episodes were treated with 1,000 mg of intravenous methylprednisolone on three consecutive days. Continuous or second rejection episodes were treated similarly. If there was still evidence of ongoing rejection after two courses of intravenous bolus steroids, therapy was changed to azathioprine and steroids. Antilymphocyte globulin was not used. Trough serum levels of cyclosporine were measured by a standard radioimmunoassay. From mid-1982 the levels were determined routinely three times per week. The dosage of cyclosporine was adjusted to avoid very high (1,000 ng per milliliter) and very low (100 ng per milliliter) though serum levels. In patients suspected of having cyclosporine-induced nephrotoxicity, the dose was reduced, provided that rejection, acute tubular necrosis, and mechanical obstruction were excluded. A fall in the serum creatinine level in response to a lower dose of cyclosporine was considered evidence of nephrotoxicity.

SOURCE: Merion RM, et al., 1984.

It is nearly impossible to describe fully the numerous variations of drug protocols that have been followed over the past several years, but all protocols which include cyclosporine call for maintenance doses to be continued throughout the patient's lifetime. Only recently has still another cyclosporine protocol been suggested. Under this protocol patients would be placed on maintenance doses of cyclosporine for the first three months posttransplant and then at that point be placed on conventional therapy (Morris et al., 1983).

Over time it is becoming apparent that renal transplantation is no longer simply a single modality. In the future, specific patient selection protocols are likely to be developed as well as unique immunosuppressive protocols for each of the patient subgroups. While some patient subgroups are likely to benefit greatly from cyclosporine, the drug may prove inappropriate for other patient subgroups. In short, the variety of current drug protocols in use suggests that attention will soon focus on patient selection protocols and the application of particular immunosuppressive protocols to these patient subgroups based upon various prognostic factors.

b. Patient and Graft Survival. Given numerous recently published reports on renal transplant patient and graft survival, one must conclude that the evidence concerning cyclosporine as a primary immunosuppressive agent is inconclusive. Najarian and colleagues at Minnesota (1983a; 1983b) reporting on the results of a prospective randomized trial of 137 patients comparing cyclosporine and prednisone with conventional immunosuppression concluded that there were "...no significant differences in patient or graft survival when the two groups are compared, no matter what the donor source or the presence

or absence of diabetes." Overall graft survival at 22 months was 83.5% with cyclosporine therapy and 82.3% with conventional therapy. Cadaveric donor organs had 84% survival for cyclosporine, and 80% graft survival for conventional therapy. Patients mismatched, but with related donors had 80% survival and 87% graft function. Among nondiabetic recipients, those treated with cyclosporine had a 90%, 18-month graft function, versus 80% graft function in those treated with conventional therapy.

Minnesota's results have been discounted because their conventional therapy is somewhat different from that used by other renal transplant programs. In particular, they have traditionally used what is referred to as "triple drug therapy" consisting of antilymphoblast globulin, prednisone, and azathioprine. Many programs use only prednisone and azathioprine. In addition, the Minnesota group includes splenectomy and pretransplant blood transfusions (at least 5 random-type-specific), but all patients in their prospective trial are subjected to these procedures. In short, it is generally believed that Minnesota achieves, perhaps, the best results obtainable under conventional therapy, whereas there is considerable room for improvement in the results of other programs.

Hakala et al. (1983) at the University of Pittsburgh have also reported the results of a randomized study of 41 "high-risk" patients, 21 of whom were randomized to the cyclosporine-prednisone group and 20 to the azathioprine-prednisone group. All patients had received at least 3 units of type-specific whole blood prior to transplant. One year graft survival for the cyclosporine group was 91%, and for the azathioprine group, 56%. Two patients under the

cyclosporine protocol lost their kidneys while nine patients treated with azathioprine did. At 12 months followup, there were no deaths in either group. The authors of the report conclude that "...this study confirms the potential usefulness of cyclosporine-A and low dose steroids to enable a high rate of graft survival..."

The Canadian Multicentre Transplant Study Group (1983) reports that in their randomized clinical trial of cyclosporine in cadaveric renal transplantation in 209 recipients both graft and patient survival were different although only graft survival was significantly so. Predicted graft survival at one year was 80.4% in patients receiving cyclosporine and 64.0% in those receiving conventional therapy ($p = 0.003$). Predicted patient survival at one-year was 96.6% in patients given cyclosporine and 86.4% in those given conventional therapy. In addition, the authors of this report indicate that among cyclosporine patients, graft survival was affected detrimentally if the kidney was perfused by machine for longer than 24 hours or if the surgical anastomosis took longer than 45 minutes. The conventional group positively benefitted from five or more blood transfusions.

As noted above, in the Canadian trial, conventional therapy varied across transplant centers. While all centers used azathioprine and prednisone, some also used antilymphocyte globulin, plasmapheresis, leukopheresis, graft irradiation, or cyclophosphamide. Therefore, cyclosporine was really tested against "best local therapy." Thus, one must conclude that even in this study patients were not subjected to pure conventional therapy in a uniform and consistent manner. This may, in effect, compromise the results of the study.

More recently, the results of the one-year follow-up for the European Multicentre Trial Group (1983) have been reported. This study involves 232 recipients of renal transplants at eight European centers. One hundred seventeen (117) patients received cyclosporine as the sole immunosuppressive agent with short courses of intravenous methylprednisolone for the treatment of rejection episodes. One hundred fifteen (115) patients received azathioprine and prednisone for immunosuppression. Graft survival, at one year, in the cyclosporine group has been 72% and 52% in the conventional group. Crossover has been a problem in this study since 24 of 84 patients in the cyclosporine group with functioning grafts at one year had been changed to azathioprine and prednisone, and one patient had had prednisolone added to cyclosporine therapy. The remaining 59 patients continued to receive cyclosporine as their sole immunosuppressive agent. In the European Trial, one-year patient survival was 94% in the cyclosporine group and 92% in the conventional group.

The European Trial differs from other trials in that cyclosporine was not supplemented with steroids. The authors report that "...because of the danger of over immunosuppression in patients receiving cyclosporine and because of the great interest in steroid-free immunosuppression, we elected to give cyclosporine without maintenance steroids." Like the Canadians, however, the Europeans also allowed each participating transplant center to continue to use their best "conventional" protocol assuming that the study results would not be biased.

Finally, the Cambridge group (Merion et al., 1984) concluded that although patient survival was better with cyclosporine then

conventional therapy, the difference was not significant. They report that at one year, actuarial patient survival in the cyclosporine group was 88 percent, as compared with 76 percent in the group receiving conventional therapy. At three years, patient survival was 86 and 76 percent, respectively.

With regards to graft survival, at one year the Cambridge group reported 77 percent for the cyclosporine group and 62 percent in the group receiving conventional therapy. At three years, graft survival was still 62 percent in the group treated with conventional therapy, whereas it was 70 percent in the cyclosporine group. Again, however, these differences were not statistically significant.

c. Infection and Rejection. The results of the foregoing studies are somewhat more, though not entirely, consistent with regard to infection and rejection episodes. It is often argued that the real benefits of cyclosporine are the lowered rates of infection and rejection associated with its use (Ho et al., 1983). Patient and graft survival, perhaps due to inconsistent results, often appear to be secondary considerations.

Najarian and his associates (1983) report that only 12 of the 70 patients (17%) in their prospective randomized trial experienced acute rejection episodes, whereas 36 of the 67 conventionally treated patients did so (54%) ($p = 0.001$). Their results also show that cyclosporine patients had fewer multiple rejection episodes despite the fact the corticosteroid dose for these patients was one-half that of the conventionally treated patients.

The Minnesota group also reports a much lower rate of infection among patients treated with cyclosporine and prednisone than

those on conventional therapy (Najarian et al., 1983a; Peterson et al., 1983). Only 2 of 70 cyclosporine-treated patients developed overt cytomegalovirus (CMV) disease (3%). During the same time, their analyses revealed that 22 of 67 conventionally treated patients developed CMV (33%). In 6 cases the CMV was lethal. In addition, there was a less than 50% incidence of bacterial, fungal, and non-CMV viral infection in the cyclosporine treated patients ($p = .05$).

As a result of less frequent episodes of infection and rejection, cyclosporine patients were less frequently hospitalized than patients on conventional therapy. Seventy-three percent of the patients on conventional therapy required posttransplant hospitalization while 50% of the cyclosporine patients did.

The Pittsburgh group has also reported a much lower rate of infection among cyclosporine-treated patients (Hakala et al., 1983). A comparison of the infection rates between the two groups shows a rate twice as high for patients on conventional therapy. In addition, the authors report that most infections encountered among the cyclosporine patients were less serious.

Results from the Canadian trial show some differences in the rate of infection among patients on cyclosporine and those receiving conventional therapy. CMV infections were substantially less of a problem among cyclosporine patients, but other infections were not so startingly different. Moreover, probably none of the differences in infection episodes presented in Table 4-7 are statistically significantly different.

Table 4-7
Infectious Complications Among Renal Transplant Patients
on Conventional Therapy and Cyclosporine

COMPLICATION	CONVENTIONAL TREATMENT (No. of complications)	CYCLOSPORINE TREATMENT (No. of complications)
Septicemia	8	4
Abscesses	7	2
Systemic fungal infection	2	1
Local fungal infection (candidiasis)	10	8
Cytomegalovirus	9	2
Other viral infection	18	16
Urinary tract infections	26	32
Wound and skin infections	10	9
Pneumonia	6	6
Other	3	1

SOURCE: Canadian Multicentre Transplant Study Group, 1983.

Results from the Canadian Trial concerning graft rejection revealed no statistically significant differences. One hundered fifty-nine (159) episodes of graft rejection were treated in the cyclosporine group, compared with 157 in the conventional therapy group--an average of 1.5 episodes per patient in both groups. The authors report that even when number of patient-days at risk and time after transplantation were taken into account, the incidence of rejection episodes was not significantly different ($p = 0.23$).

The most recent report from the European Trial reveals there was no difference in the frequency of bacterial, viral, or fungal infections between the cyclosporine-treated and the conventional therapy groups. However, very little data are presented on rejection episodes. Rejection is mentioned only insofar that it was the reason 18 patients of 117 were switched to conventional therapy. Quite surprisingly, 40 of the 117 cyclosporine patients were eventually switched to conventional therapy.

The Cambridge group reports that 61 percent of the patients receiving cyclosporine in their study experienced at least one episode of acute rejection (Merion et al., 1984). Thirty patients had only one acute rejection episode and 18 had more than one. In five patients, graft losses were due to irreversible acute rejection. In the conventionally treated group, 65 percent of the patients also had at least one rejection episode. Table 4-8 summarizes the results of the Cambridge trial. The authors conclude that: "We have not found that cyclosporine reduces the incidence of rejection episodes in our patients." They do note, however, that first rejection episodes among cyclosporine patients have been "significantly less severe."

Table 4-8
Occurrence and Timing of Rejection Episodes
in the Cambridge Trial

Category	No. Of Patients (%)	Median Time To First Rejection (Days)
Patients receiving cyclosporine	79 (100)	
No rejection	31 (39.2)	--
Rejection	48 (60.8)	7.5
One episode	30 (62.5)	10.0
More than one episode	18 (37.5)	6.0
Patients receiving azathioprine and steroids	29 (100)	
No rejection	10 (34.5)	--
Rejection	19 (65.5)	7.0
One episode	13 (68.4)	10.0
More than one episode	6 (31.6)	6.0

SOURCE: Merion et al., 1984:152.

Based on the foregoing, it is reasonable to conclude that in terms of absolute numbers of infection and rejection episodes, cyclosporine-treated patients have fewer than patients on conventional therapy (Merion et al., 1983). This is not always true for some infections, however, and the rejection episodes can be quite similar. Moreover, many of the differences alluded to as "significant" in the reports are not significant in a statistical sense.

d. Side Effects and Toxicity. The side effects and toxicity of cyclosporine are by no means minor problems (Macek, 1983; Blagg and Evans, 1983; Evans, 1983a). Among the major problems are nephrotoxicity, hepatotoxicity, hirsutism, tremors, CNS toxicity including seizures, gingival hyperplasia, hypertension, hemolytic anemia, thrombocytopenia, lymphoma, and lymphoproliferative diseases (Macek, 1983; Kolata, 1983). It is generally believed, however, that many of these side-effects can be reversed by giving patients lower doses of cyclosporine (Cleary et al., 1984; Starzl et al., 1984; Anonymous, 1984). Nonetheless, it is instructive to consider the results of the foregoing studies to assess the extent of these problems.

The Minnesota group reports that the only side effects they have observed are fine hair growth, a fine tremor of the upper extremity, a desquaming rash in two patients, and one patient with a fibroadenoma of the breast. Only three patients have been observed with hepatic toxicity. Nephrotoxicity remains the greatest complication with cyclosporine therapy. Only one-third of the Minnesota patients had normal renal function 3 to 4 months posttransplant.

The Pittsburgh group reports few side effects associated with cyclosporine although nephrotoxicity is the most common sequela. They report seeing two malignancies including one bowel lymphoma that was resected and a Kaposis sarcoma that resolved spontaneously on reduced cyclosporine dose. Hakala et al. (1983) underscore the fact that they see fewer cataracts, decreased Cushingoid appearance and fewer bone problems among patients on cyclosporine. These, of course, are problems experienced by patients on conventional therapy.

The Canadian Trial also documented posttransplant complications. Three patients receiving cyclosporine died, while eleven patients on conventional therapy did so. Two patients in the cyclosporine group developed cancer, while no cases of cancer were seen in the conventional therapy group. Aside from nephrotoxicity, the frequency of noninfectious complications was similar in both groups except for the incidence of renal-artery thrombosis or stenosis which developed in seven cyclosporine-treated patients and one on conventional therapy. Twelve patients on conventional therapy developed severe leukopenia but only one patient on cyclosporine did so. The frequency of other noninfectious complications is provided in Table 4-9.

The frequency of side effects in the European Trial has remained unchanged since the preliminary report (European Multicentre Trial Group, 1982; 1983). The most common side effects (with their frequency) in cyclosporine patients were: hirsutism (44%), fine tremor (39%), gingival hypertrophy (28%) anorexia and nausea (21%), and hyperaesthesia of the hands (11%). Again, in the European Trial these side effects were reversed with dosage reduction. Two

Table 4-9
Noninfectious Complications Among Renal Transplant Patients
On Conventional Therapy and Cyclosporine

COMPLICATION	CONVENTIONAL TREATMENT (No. of complications)	CYCLOSPORINE TREATMENT (No. of complications)
Urinary leak	4	6
Renal bleeding	8	5
Hydrocele or lymphocele	5	3
Renal artery thrombosis or stenosis	1	7
Systemic vascular complication	3	6
Hypertension	32	42
Cancer	0	2
Asceptic necrosis	3	1
Other musculoskeletal complication	3	3
Severe leukopenia	12	1
Seizures	3	4
Major neurologic complications	0	3
Minor neurologic complications	1	12
Psychiatric complications	4	3
Gastrointestinal hemorrhage	6	3
Other gastrointestinal complications	2	6
Steroid-induced diabetes	5	2
Clinical liver toxicity	4	4
Hirsutism	1	30
Gum hyperplasia	0	7
Cushingoid signs	19	17
Acne	18	13

SOURCE: Canadian Multicentre Transplant Study Group, 1983.

cyclosporine patients developed benign breast lumps and one a squamous cell carcinoma of the right cheek.

Patients on conventional therapy were not free of complications. The most common side effect was cushingoid appearance (54%). Fourteen patients (12%) had bone marrow depression, which in 9 patients required cessation of azathioprine. There were 4 cases of gastric and duodenal ulceration, 2 requiring surgery. Three patients developed moderate or severe diabetes. One patient developed a basal-cell carcinoma of the right temporal area.

The Cambridge group reports that nephrotoxicity was a problem for 10 patients receiving cyclosporine, but that these patients responded well when the dose of cyclosporine was lowered. They also report that among patients discharged with functioning grafts, the mean serum creatinine level in the cyclosporine group at discharge was not significantly higher than in the conventionally treated group. Finally, they feel that with increased experience with cyclosporine, the lymphomas among cyclosporine patients will continue to lessen. They report that since May, 1978 they have not observed a lymphoma in patients given cyclosporine.

To summarize, all studies reviewed here have shown considerable complications among patients on cyclosporine as well as those on conventional therapy (also see French et al., 1983; Kahan et al., 1984; Rosenthal et al., 1983; Sell et al., 1983; Sibley et al., 1983; Thompson et al., 1983). Perhaps these findings are the most consistent across all the trials of cyclosporine. It is generally believed, however, that the complications among cyclosporine patients diminish significantly with reduced dosages of cyclosporine. Also,

there have been several published reports on the conversion of patients on cyclosporine to conventional therapy (Flechner et al., 1983; Canafax et al., 1983; Land et al., 1983; Wood et al., 1983). Nonetheless, it is probably true that many complications associated with the use of cyclosporine and the need for conversion are in part due to the difficulty in monitoring the drug (Donatsch et al., 1981; Klintmalm et al., 1983a; 1983b; Rolles et al., 1983; White et al., 1983).

e. The Cost of Cyclosporine. Almost no data exist on the comparative costs of cyclosporine versus conventional therapy. Since the drug has only recently completed all the steps in the Food and Drug Administration (FDA) approval process, very little cost data have been accumulated. Historically, patients receiving the drug must have participated in one of the many clinical trials sponsored by Sandoz Ltd. (Basel). If a kidney transplant center was not participating in such a trial, patients undergoing a transplant had only conventional therapy available to them.

Approximately one year ago Sandoz estimated that cyclosporine would cost the individual patient between $5,000 and $6,000 per year (maintenance dosage). This figure increased subsequently to $8,000 and has recently further increased to $11,000. Conventional therapy costs on average between $1,000 and $2,000 per year. Proponents of cyclosporine have argued that while the drug is much more expensive than conventional therapy, reductions in the rates of infection and rejection due to cyclosporine mean that patient posttransplant rates of hospital admission and number of days hospitalized have been reduced considerably. If the reduction in use of hospital services is

taken into account, it is argued, cyclosporine represents a net reduction in the overall cost of transplantation. In short, the proponents argue that all posttransplant costs should be figured into the cost equation.

Unfortunately, the data required to determine if a net reduction in total posttransplant costs actually occurs is very scanty. Only recently (November 14, 1983) in testimony before the House Energy and Commerce Health Subcommittee, Ohio State University surgeon Dr. Ronald Ferguson (1983) reported on the results of a cost analysis of cyclosporine versus conventional therapy. Based on data from the Minnesota group (Ferguson was at Minnesota prior to his departure to head transplant surgery at Ohio State), Ferguson reported that initial hospital costs averaged 27% less in the cyclosporine-treated group. More specifically, Ferguson reported that the Minnesota study of 80 renal transplant recipients shows that the average initial hospital cost of the cyclosporine group (40 patients) was $24,375 compared to $33,501 in the group on conventional therapy. He also indicated that there was a 38% reduction in hospital days for cyclosporine-treated patients as well as a 52% decrease in readmissions. In a similar study of 40 patients at Ohio State, Ferguson found a 17% reduction in initial hospital costs and a 37% decrease in hospital stay, coupled with a 17% increase in the number of successful functioning grafts one year after transplant in the cyclosporine group. Ferguson concluded that, "The decrease in hospital days and the increased success rate using cyclosporine would also translate into a significant cost savings."

The actual cost savings attributable to cyclosporine is reduced when the cost of cyclosporine is taken into consideration. Since the drug was provided at no charge, the full impact of cyclosporine on overall costs is overstated. Moreover, documenting the costs of transplantation in a conceptually clear manner is quite difficult. For example, it is important to separate the costs associated with each phase of the transplant and account for all of them. Studies failing to do so frequently understate total transplant costs.

Given the high cost of cyclosporine and its reported efficacy, several proposals and bills are currently before the Congress to assist transplant recipients. Dr. Barry Kahan at the University of Texas--Houston recently testified that "At the projected costs of cyclosporine, 75% of the people on our waiting list for cadaveric kidney transplants do not have the financial resources to purchase this drug." The problem is even more acute when one considers that within the next two years, patients who have already received transplants under Sandoz-sponsored clinical trials will also be required to pay for the cyclosporine they require.

In conclusion, the cost of treating patients with cyclosporine is not well-documented. More data are required to better understand all the implications of this drug. Ultimately the cost of cyclosporine will depend upon several factors including: (1) the protocol under which the patient is transplanted, (2) the weight of the patient, and (3) markup of the drug on behalf of pharmacies. It is nonetheless clear, kidney transplant recipients have been placed in a very difficult situation--one not easily resolved. Attempts to resolve

this problem are likely to strain the Medicare program in other areas, particularly if outpatient drugs are reimbursed for on a condition-by-condition basis.

2. CYCLOSPORINE AND HEART TRANSPLANTATION

None of the ongoing studies of heart transplant recipients receiving cyclosporine are clinical trials. Two of the major heart transplant centers in the U.S. using the drug--Stanford University Medical Center and the University of Pittsburgh--simply altered their transplant protocols upon the availability of cyclosporine. In both cases, the results of clinical trials of cyclosporine in renal transplantation spurred interest in its application in heart transplantation. The Stanford group has performed a sufficiently large number of heart transplants to enable them to compare patients from the pre- and post-cyclosporine eras. At Stanford a total of 66 patients had received heart transplants and been placed on cyclosporine between December, 1980 and May, 1983. At Pittsburgh, 42 patients have been placed on cyclosporine. Because of the relatively small numbers of patients receiving heart transplants, a clinical trial with proper randomization has yet to prove feasible. Moreover, even aggregating patients across centers is a serious problem since most centers follow slightly different immunosuppressive protocols. Perhaps in the future, the feasibility of a multicenter trial of cyclosporine in heart transplantation will be demonstrated. Despite the limitations of the published reports of ongoing studies, the results are, nonetheless, worthy of consideration. At the outset, it appears cyclosporine offers advantages to heart transplant recipients that have not been substantiated in kidney transplantation.

The Stanford group has provided a summary of their patients on cyclosporine (Oyer et al., 1983b:2547). This summary is reproduced in Table 4-10. As shown here, the cumulative follow-up duration was 60.3 patient-years, with a maximum follow-up of 2.5 years. All patients in this series have received orthotopic grafts except one who received a heterotopic transplant. Two patients initially on cyclosporine underwent retransplantation.

In the Pittsburgh study (Hardesty et al., 1983), all 42 patients receiving heart transplants and placed on cyclosporine were New York Heart Association Class IV and met other published selection criteria (Baumgartner et al., 1979). Patients were between the ages of 8-54 years (median 40 years). Twenty-four patients were suffering from idiopathic cardiomyopathy and 18 from ischemic heart disease. ABO blood type was compatible in all cases, and compatibility of donor lymphocytes with recipient serum was desired and evaluated.

a. Drug Protocols. Stanford and Pittsburgh follow slightly different immunosuppressive protocols. Both Stanford and Pittsburgh have altered their own protocols on one occasion each. The Stanford protocols are summarized in Table 4-11 and that of Pittsburgh in Table 4-12. The protocols for treating rejection at each institution are provided in Tables 4-13 and 4-14. As revealed by Tables 4-13 through 4-14, there are some similarities but also distinct differences in protocols. As shown in Table 4-15, Wallwork and co-workers (1983) in England follow still a different immunosuppressive protocol, it too having been modified on one occasion.

Tagle 4-10
Cyclosporine Patient Summary At
Stanford University Medical Center

Total number of patients	66
Total number of transplants	68
Male/female	52/14
Age range (years)	13-51 (mean 36.9)
Retransplants	5
Preoperative diagnoses	
Coronary artery disease	
Native heart	21
Transplant heart	3
Cardiomyopathy	38
Viral myocarditis	1
Acute graft failure	1
Coronary embolus (pregnancy)	1
Congenital heart disease (transplant heart)	1
Valve disease with myopathy	1
Followup periods	
Range (months)	0.06-18.5
Average (months)	10.9
Cumlative duration	724 patient-months (60.3 patient-years)

SOURCE: Oyer et al., 1983b.

Table 4-11
Cyclosporine Maintenance Immunosuppression At
Stanford University Medical Center

Initial protocol	(N = 28 patients; Dec. 1980-Jan. 1982)
Cyclosporine	18 mg/kg/day (starting dose); dosage reduced by 2 mg/kg/day at monthly intervals.
Prednisone	1 mg/kg/day (initial dose); decreased to 0.2 mg/kg/day by end of 2 months.
RATG	2-4 - dose initial course
Modified Protocol	(N = 38 patients; Jan. 1982-present)
Cyclosporine	18 mg/kg/day (starting dose)*; dosage adjusted to maintain serum levels at 100-300 ng/ml.
Prednisone	1 mg/kg/day (starting dose); decreased to 0.2 mg/kg/day by end of 2 months.

*Cyclosporine starting dose attentuated in severely debilitated patients with compromised renal and hepatic function.

SOURCE: Oyer et al., 1983b.

Table 4-12
Cyclosporine Maintenance Immunosuppression Protocol At
The University of Pittsburgh

A loading dose of cyclosporine of 10 mg/kg is given prior to transplantation. Following transplantation, the maximal tolerated dose is given in two equally divided portions at 12 hour intervals. The dose is often limited by renal toxicity, less commonly by hepatic toxicity. The maintenance dose is usually adjusted so that the creatinine is 2 mg/kg/day is achieved. Whole blood levels of cyclosporine (measured by high-performance liquid chromotography, are monitored to achieve trough levels of 250-500 ng/ml.

Large initial doses of steroids are rapidly tapered to maintenace levels. Methylprednisolone (1g) is given as circulation is restored to the donor heart during transplantation. Prednisone (200 mg/day), in two divided doses, is started after operation, and the daily dose is reduced by 20 mg each day to a maintenance dose of 20 mg daily by the tenth day. If oral medication is not tolerated, an equivalent dose of methylprednisolone is given intravenously.

SOURCE: Hardesty et al, 1983:2553.

Table 4-13

Treatment of Rejection at Stanford University Medical Center

Rejection episodes are usually treated either with pulsed methylprednisolone therapy (1,000 mg daily intravenously for 3 days), holding constant the oral corticosteroid dosage, or with augmentation of oral prednisone dose to 100 mg/day, followed by tapering to near previous maintenance levels during the subsequent 2 weeks. RATG has been reserved only for those episodes that remain uncontrolled after at least two courses of pulse therapy with methylprednisolone or when histologic changes are observed to be rapidly progressive or unusually severe.

SOURCE: Oyer et al., 1983b.

Table 4-14
Treatment of Rejection at the University of Pittsburgh

To treat rejection, hydrocortisone (1 g i.v.) is given, usually without alteration of the dose of prednisone. The number and frequency of pulses varies, depending on the degree of rejection as determined by endomyocardial biopsy. Severe rejection is treated with three daily doses of hydrocortisone; less severe rejection is treated with pulsed doses at 3-, 5-, or 7-day intervals.

SOURCE: Hardesty et al., 1983:2553.

Table 4-15

Cyclosporine Maintenance Immunosuppression At Papworth Hospital

	PROTOCOL I (PATIENTS 1-6)			PROTOCOL II (PATIENTS 7-21)		
	CYCLOSPORINE	PREDNISOLOGNE	ATG	CYCLOSPORINE*	PREDNISOLONE	ATG
INITIAL	18 mg/kg/day	500 mg i.v. 125 mg i.v. x 3 0.3 mg/kg/day	---	18 mg/kg/day p.o.	500 mg i.v. 125 mg i.v. x 3 1 mg/kg/day	Horse i.v., 10 days (T cells = 10%)
MAINTENANCE	Reduce weekly by 2 mg/kg/day to 10 mg/kg/day	0.3 mg/kg/day	---	Reduce weekly by 2 mg/kg/day to 10 mg/kg/day	1 mg/kg/day to 0.3 mg/kg/day at 2 weeks	---

*Cyclosporine dose adjusted according to renal function and trough serum level (200-500 ng/ml).

SOURCE: Wallwork et al., 1983.

With increased experience these protocols are likely to be altered in the future. One of the more significant developments has been a noticeable reduction the incidence of lymphoma associated with a reduction in the overall level of immunosuppression.

b. Patient and Graft Survival. As noted above, only Stanford has transplanted a sufficiently large number of patients under conventional therapy and cyclosporine protocols to make meaningful comparisons possible. In a most recent report, 99 consecutive patients who underwent cardiac transplantation between 1976 and 1980 and received azathioprine immunosuppression were compared to those who received cyclosporine in order to assess the advantages and disadvantages of the latter agent (Oyer et al., 1983b).

In heart transplantation, except in a few instances where retransplantation has occurred, patient and graft survival are equivalent. At Stanford the number of deaths due to acute rejection among cyclosporine patients and azathioprine patients are reproduced in Table 4-16. Patient survival rates for one and two years for the cyclosporine patients are as follows: one-year, 81%, and two-year, 75% (personal communication with Philip E. Oyer, M.D.). The equivalent patient survival rates for patients receiving conventional therapy are as follows: one-year, 63% and two-year, 56%.

The Pittsburgh group has also reported their results on patient mortality among cyclosporine patients (Hardesty et al., 1983). They report that the cumulative survival of their initial 23 patients at one year was 61%, and at two years 41%. Among the 19 patients for whom "rescue therapy" was used for myocyte necrosis not responsive to pulse therapy with steroids, the cumulative survival was

Table 4-16
Causes of Death For Heart Transplant Recipients At
Stanford University Medical Center

CAUSE OF DEATH	AZATHIOPRINE PATIENTS (N = 99)	CYCLOSPORINE PATIENTS (N = 66)
Infection	40	5
Rejection	10	1
Malignancy	3	2
Graft Athersclerosis	1	2
Pulmonary Hypertension	2	1
Sudden Death	3	0
Pulmonary Embolus	1	0
Cardiomyopathy	1	0
Acute Graft Failure	0	1
CVA	0	1
Cerebral Edema	0	1
TOTAL	61	14

SOURCE: Oyer et al., 1983b.

79% at nine months. They report that three deaths resulted from acute rejection within the first three months in the first group of patients and one occurred in the second group. Their initial series contained four deaths at 8-13 months due to chronic rejection and obliterative coronary artery disease.

Infection was a factor in the cause of death of four patients (4/42). Hardesty et al. (1983) report that two other factors, neurological complications and selection of patients, were responsible for the remaining deaths. These factors appeared to be related in that neurologic complications occurred primarily in the patients who were most severely ill prior to operation.

c. Infection and Rejection. Oyer et al. (1983b) report that although the overall incidence of infection among cyclosporine patients was slightly lower than patients on conventional therapy, these differences were not significant. They have observed four categories of infection among cyclosporine patients--bacterial, viral, fungal, and nocardial (also see Baumgartner, 1983).

Oyer et al. (1983b) note that " As in the case of rejection (discussed above) the incidence of infection was only modestly reduced in comparison to patients treated with azathioprine; however, the mortality observed among those receiving CsA was substantially lower." Among the cyclosporine patients who died of infection, two deaths resulted from bacterial infection, two from fungal infection, and one from viral (cytomegalovirus) pneumonia.

Hardesty et al. (1983) reported that in their series three patients with acute rejection died within three months of transplantation, and four died of chronic rejection and restrictive

cardiomyopathy at 8-13 months. Two of the latter died unexpectedly with an acute myocardial infarction.

At Pittsburgh, infection episodes in 33 patients were monitored for a mean period of 9 months and a minimum period of 3 months. As shown in Table 4-17, reproduced from Hardesty et al. (1983:2556), the rate of infection decreased over time. Hardesty and co-workers report that herpes viral infections, bacterial pnemonia, and other intrathoracic infections (empyemy, mediastinitis) account for the majority of infection-related deaths (see Table 4-18 reproduced from Hardesty et al., 1983).

Based on the studies completed thus far, it is evident that diagnosis and treatment of rejection is not a simple matter in heart transplant recipients, although diagnosis is clearly more difficult in renal transplantation. Heart transplantation benefits from the availability of the Caves-Schultz biotome used for endomyocardial biopsies. Other techniques previously used for diagnosing rejection among patients on conventional therapy--electrocardiographic voltage, arrhythmia, clinical criteria of low cardiac output, and ventricular diastolic gallop--have all proven to be of limited value in the early diagnosis of rejection.

d. Side-Effects and Toxicity. As in renal transplantation, cyclosporine has also been found to pose serious side-effects for heart transplant recipients, although, once again these are dose-related to a large extent. Oyer et al. (1983b) report that most patients have exhibited mild degradation of renal function, with serum creatinine ranging from 1.5 - 2.5 mg/dl. They note that four patients, "all of whom exhibited severe cardiogenic renal and hepatic

Table 4-17
Infection Rates Per Quarter At The
University of Pittsburgh

QUARTER	EPISODES PER PATIENT	NUMBER OF PATIENTS
1	0.82	33
2	0.58	26
3	0.17	26
4	0.31	16
4	0.10	10

SOURCE: Hardesty et al., 1983:2556.

Table 4-18
Symptomatic Infections At The
University of Pittsburgh

INFECTION	EPISODES	NUMBER OF PATIENTS	DEATHS
Epstein-Barr cytomegalic virus	11	10	4
Bacterial pneumonia	10	9	2
Herpes simplex virus	8	8	0
Intraabdominal	5	4	1
Herpes zoster	3	3	0
Other intrathoracic	3	3	1
Mediastinal	3	3	0
Urinary Tract	2	2	0
Central nervous system	1	1	0
Disseminated toxoplasmosis	1	1	1
Pneumocystis	1	1	0
Otitis	1	1	0
Primary bacteremia	2	1	0

SOURCE: Hardesty et al., 1983:2556

dysfunction preoperatively," required hemodialysis during the first two weeks following surgery, although all recovered adequate renal function thereafter.

A second side effect believed to be associated with the administration of cyclosporine is the development of hypertension in most patients, often within one month postoperatively. This contrasts with patients on conventional therapy--only about 20 percent of whom develop hypertension.

A third effect associated with cyclosporine which may influence negatively the late outcomes of heart transplant recipients is the development of a form of myocardial fibrosis which has been observed to occur as early as 2-4 weeks after transplantation. As of now, the "long-term importance of the myocardial fibrosis observed in CsA-treated cardiac recipients remains undefined" (Oyer et al., 1983b).

Finally, lymphoproliferative disease remains a concern. At Stanford, six patients have developed lymphomas. Two resulted in death and one was diagnosed after death at the time of autopsy.

The Pittsburgh group reports a similar experience with side-effects. In their series, one patient has developed a monoclonal mixed histiocytic-lymphocytic lymphoma ultimately resulting in his death. Hardesty et al. (1983) also report the development of hypertension in their patients usually in the first operative week. Other troublesome adverse reactions they observed included hirsutism, a fine tremor of the upper extremities, nasal congestion, hyperplasia of the gums, and transient gastrointestinal ileus. Finally, convulsions occurred in 11 of 43 patients.

e. The Cost of Cyclosporine. As in kidney transplantation, there have been few studies of the costs associated with cyclosporine in the case of heart transplantation. The Stanford group has, however, directed their attention to this issue from time to time (see Pennock et al., 1982; Oyer et al., 1983b). Since length of hospital stay is a key component in the cost of heart transplantation, it is of interest to attempt to decipher if there are differences between patients on cyclosporine and those on conventional therapy. Wallwork and co-workers (1983) have specifically addressed the issue of length of hospital stay in their study of 21 patients. They found that in-hospital stay has been reduced for cyclosporine patients compared with azathioprine-based immunosuppressive therapy (see Table 4-19). They also note that within this overall reduction of in-hospital stay, the average time spent "barrier-nursed" in intensive care has been reduced from 28 to 10 days. They attribute this reduction in length of stay to the "steroid-sparing effect of CsA-based immunosuppression."

The Stanford group (Oyer et al., 1983b) has also analyzed differences in length of stay for patients on cyclosporine compared with those on conventional therapy. Their findings are similar to those of Wallwork et al. (1983). They note that with a reduction in the posttransplant complications attributable to the use of cyclosporine "...time required in the intensive care unit and in the overall hospitalization period after transplantation (43 hospital days for CsA patients versus 72 days for azathioprine patients). Oyer et al. (1983b) then go on to examine the implications of this for the total cost of heart transplantation concluding that: "The overall mean cost of the transplant hospitalization has; as a consequence,

Table 4-19
A Comparison of Length of Hospital Stay (Days)
At Papworth Hospital

IMMUNOSUPPRESSIVE PROTOCOL	MEAN LENGTH OF STAY	MEDIAN LENGTH OF STAY
Conventional Immunosuppression	81	75
Cyclosporine	51	44

SOURCE: Wallwork et al., 1983.

been substantially reduced, from $100,000 ± $47,000 for patients treated with azathioprine to $72,000 ± $38,000 for those who received CsA (and for whom such cost data are currently available, N = 48)." Omitted from consideration here are the costs of cyclosporine itself which has been supplied at no charge to Stanford patients by Sandoz, Ltd. This practice has now changed, thus, adding to the total cost of cyclosporine-treated heart transplantation. Further attention is directed to the cost implications of cyclosporine in Chapters 28-30 of this report.

F. CONCLUSION

This chapter has provided an extensive overview of immunosuppressive agents and techniques with particular attention directed to cyclosporine--the newest of immunosuppressive agents. The historical review demonstrated that developments in immunosuppression have been slow and that the primary problem with currently available drugs and techniques is their nonspecificity. Cyclosporine has some potential to alter this situation as further syntheses of the drug may produce a more specific immunosuppressive agent. While cyclosporine holds promise for the future, the drug must be viewed with cautious optimism (Evans, 1984). The results of studies in which cyclosporine is compared with conventional therapy are inconclusive and the observed side-effects of the drug can be devastating. This has prompted Assistant Secretary Dr. Edward Brandt (1984) of the Department of Health and Human Services to observe that there "...appears no doubt at all in the hands of the investigators carrying out the studies on cyclosporine that it is at least a satisfactory as

the alternative regimens," but "...whether it will prove to have great advantages over alternatives must be considered uncertain at this time." He concluded his remarks by noting that "...we remain cautiously optimistic about its potential in kidney, liver, and heart transplants.

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CHAPTER 5

THE HEART TRANSPLANT RECIPIENT SURVEY

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A. INTRODUCTION

In order to obtain the data required to meet the objectives of the National Heart Transplantation Study, several primary data collection efforts were undertaken. The data obtained in these surveys were not available through any existing or secondary sources. Although not all are described in this Chapter, five separate data collection efforts were conducted. They are as follows:

- a survey of living heart transplant recipients
- a survey of family or household members of living heart transplant recipients
- a survey of family or household members of deceased heart transplant recipients
- data abstraction of medical and hospital records of recipients
- data abstraction of medical and hospital records of nonrecipients

Each of these particular data collection efforts is more fully described in this and subsequent chapters.

To meet the primary objectives of the study, data on all aspects of heart transplantation were required. Of primary importance were data on the social and economic costs and benefits of the procedure. The best sources for some of these data were clearly the medical and hospital records maintained by each of the participating heart transplant centers (University of Arizona Health Sciences Center, Columbia Presbyterian Medical Center, Medical College of Virginia, University of Minnesota, University of Pittsburgh, and Stanford University Medical Center). Relevant medical history and treatment data as well as financial data were abstracted from these records, as

described in Chapter 6. It was, however, clear at the outset of the study that these records would be inadequate to answer numerous questions about heart transplant recipients and their families. In particular, data had to be collected on the quality of life of heart transplant recipients, the impact of the heart transplant on their family, their ability to cover expenses associated with the transplant, and their feelings about the experience they had been through. Such data could only be obtained through a comprehensive survey of living heart transplant recipients. This Chapter describes the procedures that were followed in conducting the Heart Transplant Recipient Survey.

B. THE HEART TRANSPLANT RECIPIENT SURVEY

As described above, the Heart Transplant Recipient Survey was intended to be a very comprehensive data collection effort. The survey was conducted with the help of the six participating transplant programs. Formerly some programs, such as the Stanford University Medical Center, had been reluctant to have their patients participate in such studies. The primary reason for this was a concern about patient anonymity and data confidentiality. Given the relatively small number of living heart transplant recipients, they constitute a novel group to study. This, of course, places their anonymity in jeopardy. Fortunately, for purposes of this study, each of the participating heart transplant centers had few, if any, misgivings about asking their patients to participate in the study. All centers were extremely cooperative and went out of their way to facilitate the data collection effort.

1. SAMPLE DESIGN

Except for patients under 18 years of age (N = 8) and those who were currently residing outside the United States (N = 6), all persons who had received heart transplants at the six centers and who were still living were considered eligible for the study. Patient rosters were compiled for each center. Given the small number of patients available for study, a patient census was more desirable than a sample of patients drawn from the universe of living transplant recipients. However, since there are other heart transplant programs in the U.S., the patients at the six centers that participated in the study did not constitute the universe of all living heart transplant recipients. Nonetheless, in 1983, these six programs performed 80.2 percent of all heart transplants in the country. No attempt has been made to establish what proportion of all living heart transplant recipients participated in this study, although it is clear the majority of patients did.

2. CONTENT OF THE SURVEY

For the Heart Transplant Recipient Survey, a questionnaire was developed by which the data were obtained (see Appendix 5-A). Many of the questions were identical to those included in the National Kidney Dialysis and Kidney Transplantation Study's Chronic Renal Disease Patient Interview Schedule (also conducted by Battelle). In addition to sociodemographic variables and family and household characteristics, the data collection instrument contained several questions concerning the quality of life and level of rehabilitation of recipients following transplantation, as well as the impact of the

transplant on the recipient and his or her family. In particular, questions focused on the following general areas:

- the respondent's feeling of well-being and satisfaction with life in general
- limitations of daily activities--both current limitations and limitations one year prior to transplantation
- social and family relations
- the impact of the recipient's heart condition and heart transplant on family relations
- the impact of the transplant on marital relations (if the respondent was married)
- current employment status and work history prior to transplantation
- health status--summary of recent illnesses and hospitalizations, frequency of symptoms before and after transplantation
- lifestyle--information regarding diet and exercise
- personal adjustment to the heart transplant
- experience with various government programs and rehabilitation services
- the accuracy of information provided to the recipient prior to the transplant regarding heart transplant procedures and costs
- medical expenses not reflected in hospital records including source of payment
- 1982 medical expenses and source of payment (adjusted for those transplanted after December 31, 1981)
- current regimen of routine care, including required travel
- current financial situation
- Sickness Impact Profile--a standard instrument measuring health status

The results of the Heart Transplant Recipient Survey will be incorporated throughout the remainder of this report.

3. PRETEST

In order to evaluate the survey instrument--to identify potential problems of wording, sequencing, or the sensitivity of particular questions--the questionnaire was pretested on a total of six subjects who received heart transplants at the Stanford University Medical Center. The pretest subjects represented patients who had survived from one year to ten years following transplantation. During the pretest, exact study procedures were followed, with the exception that several key investigators met with the pretest subjects at their homes or at Stanford during a followup visit. The purpose of these meetings was to debrief patients on their experience in completing the survey, and to determine how comfortable they were with the survey procedures.

The pretest subjects reported that it took approximately 90 minutes to complete the questionnaire. Patients reported that they had difficulty completing the transplant-related cost section on the pretest draft, which required that they consult their records. It was decided that this was most likely due to a Stanford policy that patients do not receive copies of their hospital bills. As a result of the pretest experience, the transplant-related cost section of the questionnaire was completely revised.

4. SURVEY PROTOCOL

Given the wide geographic distribution of living heart transplant recipients (see Table 5-1), a new technique was developed

Table 5-1
Residences of Living Heart Transplant Recipients Who Participated in the Study, By State

STATE	NUMBER RECIPIENTS
Arizona	13
Arkansas	1
California	47
Connecticut	1
District of Columbia	1
Delaware	1
Florida	6
Georgia	2
Illinois	5
Indiana	4
Iowa	2
Kentucky	1
Maryland	2
Massachusetts	1
Michigan	2
Minnesota	3
Missouri	2
Nevada	1
New Hampshire	1
New Jersey	3
New Mexico	3
New York	7
North Carolina	1
North Dakota	1
Ohio	6
Oklahoma	1
Pennsylvania	23
Rhode Island	1
South Dakota	2
Tennessee	5
Texas	7
Vermont	2
Virginia	3
Washington	2
West Virginia	2
Wisconsin	6
Wyoming	1
	172

for data collection. We refer to this technique as the "telephone-assisted mail survey." We developed the technique because of our concern about overall data collection costs. With transplant recipients living in 37 different states, in-person interviews would have been prohibitively expensive. To our knowledge, the technique, developed specifically for the National Heart Transplantation Study, has not been applied previously elsewhere.

The survey and data processing protocol consisted of three steps: (1) initial contact with heart transplant recipients, (2) data collection, and (3) data processing. As noted above, each heart transplant program was asked to provide us with a complete roster of all living heart transplant recipients. A copy of the form on which the patient rosters were recorded is attached as Appendix 5-B. Excluding patients under age 18 and patients residing outside the U.S., we assigned study identification numbers to each recipient and compiled lists of the recipients to be contacted for participation in the study. These lists, along with a supply of general information forms (see Appendix 5-C), were then sent to the respective transplant centers. A transplant center staff member then telephoned each recipient to seek their participation in the study. The purpose of this initial phone call was to (1) explain the objectives of the study, (2) obtain verbal consent from the recipient to participate in the study, and (3) identify a specific family or household member to complete a family or household member questionnaire. Based on these initial phone calls, the staff member completed a General Information Form For Living Heart Transplant Recipients and their Family or Household Member Respondents for each recipient. This form provided

Battelle with the recipient's name, address, phone number and verbal consent to participate. As well, the form gave Battelle the name, address, phone number, verbal consent to participate, and relationship to the recipient of a family or household member. In this way, lists of participating recipients from each center were compiled for use in the data collection.

A contact summary form was then established for each recipient. The form was used to record all dates and reasons for communication with the recipient, as well as the date the survey packet was mailed and the date it was returned (see Appendix 5-D). The survey packets were then sent to the recipients who agreed to participate in the study. The packet contained (1) a general consent form to be signed by the respondent (see Appendix 5-E), (2) a consent form authorizing the review of medical records and hospital billing information to be signed by the respondent (see Appendix 5-F), (3) a request form for a summary of study results (see Appendix 5-G), (4) a small return envelope for the consent forms and the request form, (5) the Heart Transplant Recipient Questionnaire stamped with the recipient's study identification number, (6) a large return envelope for the questionnaire and, (7) a cover letter (see Appendix 5-H). This letter explained the purpose of the study, gave instructions for completing and returning the survey materials, and told respondents to expect a telephone call from a survey specialist at Battelle approximately one week after receiving the survey materials. The purpose of this call was to confirm that the respondents had received the packet and to answer any questions that arose while the patient was completing the questionnaire. The letter also encouraged

respondents to call us collect if they had any questions, giving them the name and telephone number of persons to contact.

Four survey specialists were assigned to be the contact persons for each of the transplant centers. Each specialist was designated with specific responsibility for each center. The assignments were as follows:

. Arizona Health Sciences Center	Judith Raab
. Columbia Presbyterian Medical Center	Judith Raab
. Medical College of Virginia	Lair Showalter
. University of Minnesota	Cynthia Livak
. University of Pittsburgh	Lisa Bowen
. Stanford University Medical Center	Lisa Bowen, Cynthia Livak, Judith Raab, Lair Showalter

Each specialist contacted the transplant recipients from their assigned centers approximately one week after the survey packets were mailed to answer any questions. If the respondent had received the packet, but had not yet looked at it, a time in the next week was decided upon for the specialist to call again. If the respondent had not received the survey packet, another packet was sent. As completed questionnaires were returned by respondents, the date received was recorded on the contact form. The date was also stamped on the questionnaire, consent forms, and the request for survey results. To maintain anonymity, consent forms and requests for study results were returned to Battelle in separate envelopes and filed separately from the questionnaires. From the first mailing of packets to keypunching

the data, charts were used to record the stages of data collection as they were completed.

The returned questionnaires were coded and edited manually by the assigned survey specialist soon after they were received. Because the questionnaire consisted primarily of closed-ended items that were precoded, coding efforts and potential transcription errors were minimized. Quality control was maintained through weekly meetings to discuss questions, resolve problems, and amend the coding key as necessary. To solve problems of incomplete information, phone calls were made to the respondents. If completed questionnaires were not received within three weeks, additional phone calls were made to answer questions and encourage respondents to complete and return the questionnaire. Thus, every effort was taken to make the data as complete and accurate as possible.

When the majority of questionnaires had been received and coded, and questions had been resolved through phone calls to the respondents, the survey specialists verified each others' work and resolved discrepancies in coding. Several additional calls were made to recipients for whom no questionnaire had been received. Some respondents refused (N = 4) and others reported they had completed and sent the questionnaire, but it was never received. (It was assumed that these survey instruments were lost in the mail and almost all of these respondents were willing to complete another questionnaire.) The verified instruments were then keypunched and 100% verified, a computer data file was created and the data were cleaned for analysis.

5. CONSENT AND CONFIDENTIALITY PROCEDURES

As described above, initial contact with heart transplant recipients was made by a member of the transplant center staff. Only those individuals who gave their verbal consent to participate were sent survey materials.

As noted above, prior to completing the questionnaire, transplant recipients were asked to sign two consent forms, one form acknowledging their willingness to participate in the study (General Recipient Consent Form), and a second form giving permission to extract information from hospital and medical records (Authorization For Review of Medical Records and Hospital Billing Information). Respondents were fully informed of the nature and purposes of the study and the uses which were to be made of the data. The consent forms provided Battelle with a written acknowledgement from each individual indicating that they have been informed of:

- the objectives of the study
- the procedures to be followed
- measures to be taken to ensure the information they provide is kept confidential
- possible discomforts or risks associated with their participation
- where to direct their inquiries concerning the study
- the purely voluntary nature of their participation and their freedom to refuse any part or discontinue participation in the study at any time.

In a cover letter, respondents were requested to carefully read, and if willing to participate, sign the consent forms and return them to Battelle separately from the survey instrument.

While they were signed by the participant, the consent forms did not contain the participant's identification number. The recipient questionnaire was the only component of the packet marked with the participant's identification number. It did not, however, ask for the participant's name, address, or other information which could be used to directly identify individuals or link their identification numbers with their names.

When returned, the completed questionnaires were filed separately from the consent forms. Except when necessary to match individual information, the lists of participants and their corresponding identification numbers were kept separately from all data files. All records were maintained in secure storage areas that were accessible only to authorized personnel. The resulting data files identified participants only by identification number. This procedure has protected the anonymity of the participant's questionnaire responses and all other information obtained concerning the recipient.

C. RESPONSE RATES

At the outset of the study we were very concerned about the survey response rate. Much of this concern was attributable to our inexperience with a new data collection technique--the telephone-assisted mail survey. However, the response rate which we achieved using the telephone-assisted mail survey was very high, certainly

comparable to those achieved in other studies using in-person interviews.

As shown in Table 5-2, of a total of 192 living heart transplant recipients from the six participating centers, 175 (91%) were eligible to participate in the study. Those who were considered ineligible included recipients less than 18 years of age, those residing outside the country, and those who died after the roster was compiled. All 175 eligible recipients were contacted by their respective transplant centers concerning participation in the study and 172 (98%) agreed to participate. The survey packets were mailed to these 172 participants and 152 (88%) completed questionnaires were returned. For various reasons, including respondents refusing to fill out the questionnaire after receiving it and completed questionnaires being lost in the return mail, we failed to receive 20 questionnaires (see Table 5-3).

D. CONCLUSION

Our experience with the telephone-assisted mail survey technique was very positive. For very specific applications, we feel this technique is worthy of further consideration as an alternative to very expensive in-person interviews. As described above, the data collection instrument for the National Heart Transplantation Study was comprehensive and complicated to complete. Participants were requested to provide data on nearly every aspect of heart transplantation, however this did not appear to detract from the efficacy of the technique. Moreover, most heart transplant recipients were very enthusiastic about the study which undoubtedly contributed to the high response rate.

Table 5-2
Living Heart Transplant Recipient Survey Participants

Center	Total Number Recipients	Number Living Recipients	Less Than 18 Years of Age	Reside Out of Country	Died After Roster Was Completed	Contacted to Participate	Refused to Participate	Number of Questionnaires Mailed
Arizona	40	22	2	0	1	19	1	18
Columbia	29	9	0	0	0	9	0	9
MCV	37	17	2	0	0	15	0	15
Minnesota	20	9	0	0	0	9	1	8
Pittsburgh	49	28	0	0	1	27	0	27
Stanford	269	107	4	6	1	96	1	95
TOTAL	444	192	8	6	3	175	3	172

Table 5-3
Living Heart Transplant Recipient Survey Response Rates

Center	Number of Questionnaires Mailed	Refused After Receiving Questionnaire	Lost In Mail	Failed to Return Questinnaire	Completed Questionnaires Returned
Arizona	18	0	0	3	15
Columbia	9	0	1	1	7
MCV	15	0	0	1	14
Minnesota	8	0	0	0	8
Pittsburgh	27	1	0	1	25
Stanford	95	3	0	9	83
TOTAL	172	4	1	15	152

APPENDIX 5-A

HEART TRANSPLANT RECIPIENT SURVEY

HEART TRANSPLANT RECIPIENT QUESTIONNAIRE

NATIONAL HEART TRANSPLANTATION STUDY*

Health and Population Study Center
Battelle Human Affairs Research Centers
4000 N.E. 41st Street
Seattle, Washington 98105
Telephone (206) 525-3130

* A project sponsored by the Office of Research and Demonstrations of the Health Care Financing Administration. Contract Number 500-81-0051. Questions concerning this study should be directed to Dr. Roger W. Evans at the Battelle Human Affairs Research Centers.

INTRODUCTION TO THE QUESTIONNAIRE

As you are now aware, the National Heart Transplantation Study is the first major study of heart transplant recipients and their family or household members. The study is concerned not only with the financial aspects, but with all aspects of heart transplantation including how well you are doing at this time. For clarity, we at the Battelle Human Affairs Research Centers in Seattle, Washington have divided the study into several major research components. These components include: (1) the need for or number of people requiring heart transplants in the United States, (2) the demonstrated value of heart transplantation as a medical procedure, (3) the availability of donor hearts, (4) the cost of performing a heart transplant and the routine medical management that occurs thereafter, (5) the quality of life enjoyed by heart transplant recipients both before and after their heart transplant, and (6) various legal and ethical dilemmas that surround heart transplantation as a medical procedure not suitable for everyone.

The Federal government is currently considering the possibility of extending various benefits to patients who in the future may need a heart transplant. In order to fully understand the implications of doing so, the U.S. Congress mandated that a thorough study of heart transplantation be undertaken. You are being asked to participate in this exceedingly important study along with other heart transplant recipients. The National Heart Transplantation Study intends to present an accurate and objective picture of the current status of heart transplantation in the United States. The results of this study are expected to play a key role in decisions Congress will make concerning heart transplantation.

To meet the numerous and varied objectives of the study as outlined above, this questionnaire is long and very detailed. We do not expect that you will be able to complete it in a single sitting. In fact, we ask that you complete the questionnaire over a minimum of a two-day period. You may take longer if you so desire. We suggest that you make yourself comfortable when you sit down to fill out the questionnaire and thoughtfully answer as many of the questions as you can. As described below, you may choose not to answer some questions, and for others you may have to consult your own records concerning expenses and hospital bills. Under no circumstances do we intend to overburden you with questions that are of little or no value.

Also, as part of the study a family or household member will be receiving a separate questionnaire. Similar questions will be asked of both of you. However, in your questionnaire we are interested in how **YOU** feel about your heart transplant and how **YOU** have adjusted to it. Therefore, we ask that you complete your questionnaire **WITHOUT** consulting them.

Any person who has undergone major surgery or life-saving therapy has undoubtedly given considerable thought to many difficult issues, such as the quality of their lives, the impact of their treatment on their family, the cost of their medical care, and religious and spiritual beliefs concerning life and death. Although you have probably thought about these, you may never have been asked to answer questions about them in a study such as this. Therefore, you may very well experience some discomfort in doing so. If the questions make you feel too uncomfortable you should place a collect call to Dr. Roger W. Evans at (206) 525-3130. He will be happy to discuss whatever problems you may have in completing the questionnaire.

In responding you may at times wonder about the value of the information you are asked to provide, may dislike the content of some questions, or may feel that some questions are repeated. These responses are not unexpected and merely reflect the complexity of this study. There may also be some questions which you feel are "none of our business" or that you would prefer not to

answer. If you choose not to answer a question for any reason, please indicate this by writing "NO ANSWER" beside the question so we will know that you read the question and decided not to respond. Be assured that **YOU ARE NOT REQUIRED TO ANSWER ANY QUESTION IN THIS QUESTIONNAIRE.** As in any survey, we would like you to answer as many questions as you possibly can. If too many people choose not to answer the questions, the success of the study will be jeopardized.

You will note that there are instructions beside some answer categories which tell you to skip the next questions and go to a specific question. For example:

14. Did you change your permanent residence as a result of your need for a heart transplant?

(CIRCLE ONE)

YES 01

NO ..... 02 **(GO TO Q.17)**

If you answer yes, you will go to the next question, Q. 15. If you answer no, you will skip Questions 15 and 16 and go directly to Question 17.

In order to acknowledge your willingness to participate in the study, we have enclosed two consent forms which we would like you to sign. The first consent form is called the General Consent Form and simply indicates that you are willing to answer the questions in this questionnaire. In addition to having you complete the questionnaire we would also like to obtain some information from the medical and hospital records maintained by your transplant center. To give us permission to see your medical and hospital records, you must also sign the enclosed form entitled "Authorization for Review of Medical and Hospital Records." If you choose to let us review your medical records, only information about your heart transplant will be studied.

As noted in the General Consent Form, all information we receive from you or your heart transplant center is strictly confidential. No one, including the government or your doctors, will ever be told how you responded to the questionnaire. Your name will not appear on the questionnaire. You will notice that a number has been assigned to your questionnaire--this is the **only** identifying information that will be associated with your questionnaire.

Once you have signed the consent forms you should retain the pink copy for your records and return the white and yellow copies to us with the completed questionnaire. The consent forms will be retained in a file separate from your questionnaire. More specific information on the anonymity of your responses and the confidentiality of the data is provided in the enclosed consent forms.

Within the next seven days a survey assistant at the Battelle Human Affairs Research Centers will be calling to answer any questions you may have about the National Heart Transplantation Study. It would be helpful if you would complete as much of the questionnaire as you can before you receive the call. If, however, you have questions or are particularly troubled by the questionnaire, please do not hesitate to place a collect call to us at (206) 525-3130, extension 457. We would be more than happy to discuss the study with you.

HEART TRANSPLANT RECIPIENT NUMBER _____ 1 — — — — — 6

DATE _____ 7 — — — — — 12

1. In what month and year were you first diagnosed as having a heart condition?

_____ / _____
MONTH YEAR

13 — — — 16

2. When did you receive your heart transplant? *(If you have received more than one, please enter the date of your most recent transplant.)*

_____ / _____ / _____
MONTH DAY YEAR

17 — — — — — 22

3. Have you had more than one heart transplant?

(CIRCLE ONE)

YES 01

NO 02

23 — 24

4. **IF YES,** how many heart transplants have you had?

NUMBER OF TRANSPLANTS _____

25 — 26

5. What is your year of birth?

_____
YEAR

27 — 28

6. What is your sex?

(CIRCLE ONE)

MALE 01

FEMALE 02

29 — 30

7. Which of the following best describes your racial or ethnic identification?

(CIRCLE ONE)

BLACK (NEGRO) 01

CHICANO (MEXICAN-AMERICAN) 02

NATIVE AMERICAN
(AMERICAN INDIAN, ESKIMO, ALEUT) 03

WHITE (CAUCASIAN) 04

ORIENTAL (ASIAN AMERICAN OR
PACIFIC ISLANDER) 05

OTHER (SPECIFY) _____ 06

31 32

8. What is your height?

_____ FEET and _____ INCHES

33 34

35 36

9. What is your current body weight?

_____ POUNDS

37 39

10. What is your current marital status?

(CIRCLE ONE)

MARRIED 01

WIDOWED 02

DIVORCED 03

SEPARATED 04

NEVER MARRIED 05

40 41

11. Does anyone live at your residence with you?

(CIRCLE ONE)

YES 01

NO 02

42 43

2 0 1

79 80

12. **IF YES,** for the other people living in your household, please list their relationship to you and their age.

RELATIONSHIP TO YOU	**AGE**	(Dup 1-6)
_____	_____	7 10
_____	_____	11 14
_____	_____	15 18
_____	_____	19 22
_____	_____	23 26
_____	_____	27 30
_____	_____	31 34
_____	_____	35 38
_____	_____	39 42
_____	_____	43 46

13. What type of dwelling do you live in at the present time?

(CIRCLE ONE)

SINGLE FAMILY HOME OWNED BY YOU OR YOUR FAMILY 01

SINGLE FAMILY HOME RENTED BY YOU OR YOUR FAMILY 02

UNIT IN A MULTIPLE-FAMILY DWELLING OWNED BY YOU OR YOUR FAMILY 03

UNIT IN A MULTIPLE-FAMILY DWELLING RENTED BY YOU OR YOUR FAMILY 04

HOSPITAL 05

NURSING HOME/CONVALESCENT HOME 06

RETIREMENT COMMUNITY 07

OTHER (SPECIFY) _____ 08

47 48

14. Did you change your permanent residence as a result of your need for a heart transplant?

(CIRCLE ONE)

YES 01

NO ..... 02 **(GO TO Q.17)**

49 50

15. What type of residence did you live in before you had your heart transplant?

(CIRCLE ONE)

SINGLE FAMILY HOME OWNED BY YOU OR YOUR FAMILY 01

SINGLE FAMILY HOME RENTED BY YOU OR YOUR FAMILY 02

UNIT IN A MULTIPLE-FAMILY DWELLING OWNED BY YOU OR YOUR FAMILY 03

UNIT IN A MULTIPLE-FAMILY DWELLING RENTED BY YOU OR YOUR FAMILY 04

HOSPITAL 05

NURSING HOME/CONVALESCENT HOME 06

RETIREMENT COMMUNITY 07

OTHER (SPECIFY) _____ 08

16. How was your change in residence related to your heart transplant?

(CIRCLE YES OR NO FOR EACH ITEM)

	YES	NO
A. NEEDED A LESS EXPENSIVE PLACE BECAUSE OF HIGHER MEDICAL EXPENSES	01	02
B. NEEDED A RESIDENCE CLOSER TO MEDICAL FACILITIES	01	02
C. AS A RESULT OF MY ILLNESS I HAD TO CHANGE JOBS AND I NEEDED A RESIDENCE CLOSER TO MY WORK	01	02
D. NEEDED A RESIDENCE EASIER TO MAINTAIN	01	02
E. NEEDED A RESIDENCE WITH FEWER NO STAIRS	01	02
F. OTHER (SPECIFY) _____	01	02

17. How many years of education have you completed?

YEARS _____

65 66

18. What is the highest degree you have obtained?

(CIRCLE ONE)

NEVER GRADUATED FROM HIGH SCHOOL	01
HIGH SCHOOL DIPLOMA	02
COLLEGE/UNIVERSITY DEGREE	03
ADVANCED DEGREE (M.A., M.S., Ph.D., M.D., J.D., etc.)	04

67 68

2 0 2

78 80

19. Below we have listed events that may have happened to you recently. Please indicate whether or not you have experienced these events **WITHIN THE PAST THREE MONTHS.**

(CIRCLE YES OR NO FOR EACH EVENT)

(Dup 1-6)

	YES	NO	
A. CHANGE IN RESIDENCE	01	02	7 8
B. IN-LAW TROUBLES	01	02	9 10
C. DEATH OF SPOUSE	01	02	11 12
D. DEATH OF CLOSE FAMILY MEMBER OTHER THAN SPOUSE	01	02	13 14
E. DEATH OF CLOSE FRIEND	01	02	15 16
F. GAINING A NEW FAMILY MEMBER (THROUGH BIRTH, ADOPTION, OR SOMEONE MOVING IN WITH YOU)	01	02	17 18
G. MAJOR CHANGE IN HEALTH OR BEHAVIOR OF A FAMILY MEMBER	01	02	19 20
H. MINOR VIOLATIONS OF THE LAW (TRAFFIC TICKETS, JAY WALKING, DISTURBING THE PEACE)	01	02	21 22
I. DETENTION IN JAIL OR OTHER INSTITUTION	01	02	23 24
J. MARRIAGE	01	02	25 26
K. DIVORCE	01	02	27 28
L. MARITAL SEPARATION FROM SPOUSE	01	02	29 30
M. SON OR DAUGHTER LEAVING HOME	01	02	31 32
N. TAKING A MORTGAGE OR LOAN GREATER THAN $10,000	01	02	33 34
O. TAKING A MORTGAGE OR LOAN LESS THAN $10,000	01	02	35 36
P. FORECLOSURE ON A MORTGAGE OR LOAN	01	02	37 38
Q. VACATION	01	02	39 40
R. MARITAL RECONCILIATION WITH MATE	01	02	41 42

QUALITY OF LIFE

Next we would like you to answer a few questions about your life in general; for example, how you have been feeling and your satisfaction with life.

20. During the **PAST FEW WEEKS,** did you ever feel...

(CIRCLE YES OR NO FOR EACH ITEM)

	YES	NO	
A. PARTICULARLY EXCITED OR INTERESTED IN SOMETHING?	01	02	43 44
B. SO RESTLESS THAT YOU COULDN'T SIT LONG IN A CHAIR?	01	02	45 46
C. PROUD BECAUSE SOMEONE COMPLIMENTED YOU ON SOMETHING YOU HAD DONE?	01	02	47 48
D. VERY LONELY OR REMOTE FROM OTHER PEOPLE?	01	02	49 50
E. PLEASED ABOUT HAVING ACCOMPLISHED SOMETHING?	01	02	51 52
F. BORED?	01	02	53 54
G. ON TOP OF THE WORLD?	01	02	55 56
H. DEPRESSED OR VERY UNHAPPY?	01	02	57 58
I. THAT THINGS WERE GOING YOUR WAY?	01	02	59 60
J. UPSET BECAUSE SOMEONE CRITICIZED YOU?	01	02	61 62

2 0 3
78 79 80

Now we would like for you to answer a few questions about how you have felt and how things have been within the **PAST MONTH.**

21. How have you been feeling in general during the **PAST MONTH?**

(CIRCLE ONE)

(Dup 1-6)

IN EXCELLENT SPIRITS 01

IN VERY GOOD SPIRITS 02

IN GOOD SPIRITS MOSTLY 03

UP AND DOWN IN SPIRITS A LOT 04

IN LOW SPIRITS MOSTLY 05

IN VERY LOW SPIRITS 06

— — 7 8

22. Have you been bothered by nervousness or your nerves during the **PAST MONTH?**

(CIRCLE ONE)

EXTREMELY SO—TO THE POINT WHERE YOU COULD NOT WORK OR TAKE CARE OF THINGS 01

VERY MUCH SO 02

QUITE A BIT 03

SOME—ENOUGH TO BE BOTHERED 04

A LITTLE 05

NOT AT ALL 06

— — 9 10

23. Have you been in firm control of your behavior, thoughts, emotions, **OR** feelings during the **PAST MONTH?**

(CIRCLE ONE)

YES, DEFINITELY SO	01
YES, FOR THE MOST PART	02
GENERALLY SO	03
NOT TOO WELL	04
NO, ENOUGH TO BOTHER YOU SOMEWHAT	05
NO, ENOUGH TO BOTHER YOU VERY MUCH	06

11 12

24. Have you felt so sad, discouraged, hopeless or had so many problems that you wondered if anything was worthwhile during the **PAST MONTH?**

(CIRCLE ONE)

EXTREMELY SO–TO THE POINT THAT YOU HAVE JUST ABOUT GIVEN UP	01
VERY MUCH SO	02
QUITE A BIT	03
SOME–ENOUGH TO BE BOTHERED	04
A LITTLE BIT	05
NOT AT ALL	06

13 14

25. Have you been under or felt you were under any strain, stress, or pressure during the **PAST MONTH?**

(CIRCLE ONE)

YES–ALMOST MORE PRESSURE THAN YOU COULD BEAR OR STAND	01
YES–QUITE A BIT OF PRESSURE	02
YES–SOME - MORE THAN USUAL	03
YES–SOME - BUT ABOUT USUAL	04
YES–A LITTLE	05
NOT AT ALL	06

15 16

26. How happy, satisfied, or pleased have you been with your personal life during the **PAST MONTH?**

(CIRCLE ONE)

EXTREMELY HAPPY--COULD NOT HAVE BEEN MORE SATISFIED OR PLEASED 01

VERY HAPPY 02

FAIRLY HAPPY 03

SATISFIED--PLEASED 04

SOMEWHAT DISSATISFIED 05

VERY DISSATISFIED 06

27. Have you had any reason to wonder if you were losing your mind, or losing control over the way you act, talk, think, or feel during the **PAST MONTH?**

(CIRCLE ONE)

NOT AT ALL 01

ONLY A LITTLE 02

SOME--BUT NOT ENOUGH TO BE CONCERNED OR WORRIED ABOUT 03

SOME AND A LITTLE CONCERNED ABOUT IT 04

SOME AND QUITE CONCERNED ABOUT IT 05

YES, VERY MUCH SO AND VERY CONCERNED ABOUT IT 06

28. Have you been anxious, worried, or upset during the **PAST MONTH?**

(CIRCLE ONE)

EXTREMELY SO--TO THE POINT OF BEING SICK OR ALMOST SICK 01

VERY MUCH SO 02

QUITE A BIT 03

SOME--ENOUGH TO BE BOTHERED 04

A LITTLE BIT 05

NOT AT ALL 06

29. Have you felt down-hearted and blue during the **PAST MONTH?**

(CIRCLE ONE)

ALL OF THE TIME 01
MOST OF THE TIME 02
A GOOD BIT OF THE TIME 03
SOME OF THE TIME 04
A LITTLE OF THE TIME 05
NONE OF THE TIME 06

23 24

30. Have you been feeling emotionally stable and sure of yourself during the **PAST MONTH?**

(CIRCLE ONE)

ALL OF THE TIME 01
MOST OF THE TIME 02
A GOOD BIT OF THE TIME 03
SOME OF THE TIME 04
A LITTLE OF THE TIME 05
NONE OF THE TIME 06

25 26

31. Some people feel they can run their lives pretty much the way they want to; others feel the problems of life are sometimes too big for them. Which one are you most like?

(CIRCLE ONE)

CAN RUN OWN LIFE 01
PROBLEMS OF LIFE TOO BIG 02

27 28

32. Up to now, have you been able to satisfy most of your ambitions in life or have you had to settle for less than you hoped for?

(CIRCLE ONE)

SATISFIED MOST AMBITIONS 01
HAVE HAD TO SETTLE FOR LESS 02

29 30

33. Do you think you have had a fair opportunity to make the most of your life or have you been held back in some ways?

(CIRCLE ONE)

HAVE HAD A FAIR OPPORTUNITY 01

HAVE BEEN HELD BACK 02

31 32

34. Compared to **OTHER PEOPLE YOU KNOW,** would you say that you have enjoyed your life up to now more than most people, about the same, or less than most people?

(CIRCLE ONE)

MORE 01

ABOUT THE SAME 02

LESS 03

33 34

35. Taking all things together, how would you say things are these days—would you say you're very happy, pretty happy, or not too happy?

(CIRCLE ONE)

VERY HAPPY 01

PRETTY HAPPY 02

NOT TOO HAPPY 03

35 36

36. If you were to compare your quality of life with that of **OTHER PEOPLE WHOM YOU KNOW,** would you say your quality of life is better than theirs, about the same, or lower than theirs?

(CIRCLE ONE)

BETTER 01

ABOUT THE SAME 02

LOWER 03

37 38

37. Comparing your health with that of **OTHER PEOPLE YOUR AGE,** would you say your health is better than theirs, about the same, or poorer than theirs?

(CIRCLE ONE)

BETTER 01

ABOUT THE SAME 02

POOREr 03

39 40

38. The things people have--housing, car, furniture, recreation, and the like--make up their standard of living. Some people are satisfied with their standard of living, others feel it is not as high as they would like. How satisfied are you with your standard of living?

(CIRCLE ONE)

COMPLETELY SATISFIED 01

VERY SATISFIED 02

SATISFIED 03

NEUTRAL 04

DISSATISFIED 05

VERY DISSATISFIED 06

COMPLETELY DISSATISFIED 07

41 42

39. All things considered, how would you rate your friendships--the time you spend with friends, the things you do together, the number of friends you have, as well as the particular people who are your friends?

(CIRCLE ONE)

COMPLETELY SATISFIED 01

VERY SATISFIED 02

SATISFIED 03

NEUTRAL 04

DISSATISFIED 05

VERY DISSATISFIED 06

COMPLETELY DISSATISFIED 07

43 44

40. How satisfied are you with your life as a whole these days?

(CIRCLE ONE)

COMPLETELY SATISFIED	01
VERY SATISFIED	02
SATISFIED	03
NEUTRAL	04
DISSATISFIED	05
VERY DISSATISFIED	06
COMPLETELY DISSATISFIED	07

45 46

41. All things considered, how satisfied are you with your family life--the time you spend and the things you do with members of your family?

(CIRCLE ONE)

COMPLETELY SATISFIED	01
VERY SATISFIED	02
SATISFIED	03
NEUTRAL	04
DISSATISFIED	05
VERY DISSATISFIED	06
COMPLETELY DISSATISFIED	07

47 48

42. *(FOR MARRIED OR SEPARATED PATIENTS ONLY)* How satisfied are you with your marriage?

(CIRCLE ONE)

COMPLETELY SATISFIED	01
VERY SATISFIED	02
SATISFIED	03
NEUTRAL	04
DISSATISFIED	05
VERY DISSATISFIED	06
COMPLETELY DISSATISFIED	07

49 50

43. How satisfied are you with your family's situation as far as savings and investments are concerned?

(CIRCLE ONE)

COMPLETELY SATISFIED	01
VERY SATISFIED	02
SATISFIED	03
NEUTRAL	04
DISSATISFIED	05
VERY DISSATISFIED	06
COMPLETELY DISSATISFIED	07

51 52

44. Most people get sick now and then, and others, such as yourself, have had chronic health problems. Overall, how satisfied are you with your health at this time?

(CIRCLE ONE)

COMPLETELY SATISFIED	01
VERY SATISFIED	02
SATISFIED	03
NEUTRAL	04
DISSATISFIED	05
VERY DISSATISFIED	06
COMPLETELY DISSATISFIED	07

53 54

45. Here are some words and phrases which we would like you to use to describe how you feel about your present life. For example, if you think your present life is **very** "boring," put an X in the box right next to the word "boring." If you think it is **very** "interesting," put an X in the box right next to the word "interesting." If you think it is somewhere in between, put an X where you think it belongs. **Put an X in one box on every line.**

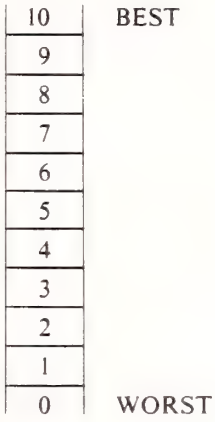
BORING	☐☐☐☐☐☐☐	INTERESTING
ENJOYABLE	☐☐☐☐☐☐☐	MISERABLE
EASY	☐☐☐☐☐☐☐	HARD
USELESS	☐☐☐☐☐☐☐	WORTHWHILE
FRIENDLY	☐☐☐☐☐☐☐	LONELY
FULL	☐☐☐☐☐☐☐	EMPTY
DISCOURAGING	☐☐☐☐☐☐☐	HOPEFUL
TIED DOWN	☐☐☐☐☐☐☐	FREE
DISAPPOINTING	☐☐☐☐☐☐☐	REWARDING
BRINGS OUT THE BEST IN ME	☐☐☐☐☐☐☐	DOESN'T GIVE ME MUCH CHANCE

2 0 4

46. Below is a picture of a ladder. At the bottom of the ladder is the **WORST** life you might reasonably expect to have. At the top is the **BEST** life you might expect to have. Of course, life from week-to-week falls somewhere in between. According to this scale, how would you rate your **BEST WEEK IN THE PAST YEAR?**

(Dup 1-6)

NUMBER_____ __ __ 7 8



47. Where on the ladder was your **WORST WEEK** during the past year--How would you rate it? *(REFER TO THE LADDER IN Q. 46)*

NUMBER_____ __ __ 9 10

48. Where was your life **FIVE YEARS AGO?** *(REFER TO THE LADDER IN Q. 46)*

NUMBER_____ __ __ 11 12

49. Where was your life one year **BEFORE YOU HAD YOUR HEART TRANSPLANT?** *(REFER TO THE LADDER IN Q. 46)*

NUMBER_____ __ __ 13 14

DAILY ACTIVITIES

We are also interested in changes that may have occurred in your daily activities since you received your heart transplant. Some recipients find that they can do more than they were doing before their transplant; others have had to limit their activities.

50. How difficult is it for you to remember what you felt like **JUST BEFORE YOU HAD THE TRANSPLANT;** that is, when you were sick with heart disease?

(CIRCLE ONE)

VERY DIFFICULT	01
SOMEWHAT DIFFICULT	02
A LITTLE DIFFICULT	03
NOT AT ALL DIFFICULT	04

15 16

51. How difficult is it for you to remember what you felt like **BEFORE YOU WERE EVER SICK WITH HEART DISEASE?**

(CIRCLE ONE)

VERY DIFFICULT	01
SOMEWHAT DIFFICULT	02
A LITTLE DIFFICULT	03
NOT AT ALL DIFFICULT	04
I HAVE ALWAYS HAD HEART DISEASE	05

17 18

Please answer the following questions for both your **CURRENT** activity AND for the **YEAR BEFORE** you received your heart transplant. The wording of these questions is slightly awkward because we are trying to cover two time periods without restating the questions.

52. When traveling around your community, does/ did someone have to assist you because of your health?

(CIRCLE YES OR NO FOR EACH TIME PERIOD)

	YES	NO	
A. CURRENTLY	01	02	19 20
B. ONE YEAR PRIOR TO TRANSPLANT	01	02	21 22

53. Do/ Did you have to stay indoors most or all of the day because of your health?

(CIRCLE YES OR NO FOR EACH TIME PERIOD)

	YES	NO	
A. CURRENTLY	01	02	23 24
B. ONE YEAR PRIOR TO TRANSPLANT	01	02	25 26

54. Are/ Were you in a bed or chair for most or all of the day because of your health?

(CIRCLE YES OR NO FOR EACH TIME PERIOD)

	YES	NO	
A. CURRENTLY	01	02	27 28
B. ONE YEAR PRIOR TO TRANSPLANT	01	02	29 30

55. Does/ Did your health limit the kind of vigorous activities you can do, such as running, lifting heavy objects, or participating in strenuous sports?

(CIRCLE YES OR NO FOR EACH TIME PERIOD)

	YES	NO	
A. CURRENTLY	01	02	31 32
B. ONE YEAR PRIOR TO TRANSPLANT	01	02	33 34

56. Do/Did you have any trouble either walking **SEVERAL BLOCKS** or climbing a **FEW FLIGHTS** of stairs, because of your health?

(CIRCLE YES OR NO FOR EACH TIME PERIOD)

	YES	NO	
A. CURRENTLY	01	02	35 36
B. ONE YEAR PRIOR TO TRANSPLANT	01	02	37 38

57. Do/Did you have trouble bending, lifting, or stooping because of your health?

(CIRCLE YES OR NO FOR EACH TIME PERIOD)

	YES	NO	
A. CURRENTLY	01	02	39 40
B. ONE YEAR PRIOR TO TRANSPLANT	01	02	41 42

58. Do/Did you have any trouble either walking **ONE BLOCK** or climbing **ONE FLIGHT** of stairs because of your health?

(CIRCLE YES OR NO FOR EACH TIME PERIOD)

	YES	NO	
A. CURRENTLY	01	02	43 44
B. ONE YEAR PRIOR TO TRANSPLANT	01	02	45 46

59. Do/Did you need help in walking such as assistance by another person or by a cane, crutches, walker, artificial limbs, or braces?

(CIRCLE YES OR NO FOR EACH TIME PERIOD)

	YES	NO	
A. CURRENTLY	01	02	47 48
B. ONE YEAR PRIOR TO TRANSPLANT	01	02	49 50

60. Are/ Were you unable to do certain kinds or amounts of work, housework, or schoolwork because of your health?

(CIRCLE YES OR NO FOR EACH TIME PERIOD)

	YES	NO	
A. CURRENTLY	01	02	51 52
B. ONE YEAR PRIOR TO TRANSPLANT	01	02	53 54

61. Does/ Did your health keep you from working at a job, doing work around the house, or going to school?

(CIRCLE YES OR NO FOR EACH TIME PERIOD)

	YES	NO	
A. CURRENTLY	01	02	55 56
B. ONE YEAR PRIOR TO TRANSPLANT	01	02	57 58

62. Do/ Did you need help with eating, dressing, bathing, or using the toilet because of your health?

(CIRCLE YES OR NO FOR EACH TIME PERIOD)

	YES	NO	
A. CURRENTLY	01	02	59 60
B. ONE YEAR PRIOR TO TRANSPLANT	01	02	61 62

63. Does/ Did your health limit you in any way from doing anything you want to do?

(CIRCLE YES OR NO FOR EACH TIME PERIOD)

	YES	NO	
A. CURRENTLY	01	02	63 64
B. ONE YEAR PRIOR TO TRANSPLANT	01	02	65 66

2 0 5
78 80

64. Does your health **NOW** limit your ability to:

(CIRCLE YES OR NO FOR EACH TASK)

(Dup 1-6)

	YES	NO	
A. REACH?	01	02	7 8
B. USE FINGERS TO GRASP OR HANDLE?	01	02	9 10
C. USE YOUR EYES FOR INSPECTION OF THINGS?	01	02	11 12
D. USE YOUR EYES FOR READING?	01	02	13 14
E. LIFT OR CARRY WEIGHTS UP TO 10 POUNDS?	01	02	15 16
F. LIFT OR CARRY WEIGHTS UP TO 25 POUNDS?	01	02	17 18
G. LIFT OR CARRY WEIGHTS UP TO 50 POUNDS?	01	02	19 20

Doctors who treat patients with heart conditions often hear about problems with sexual functioning and sexual activity from their patients. Some of these problems are related to the disease itself and others are related to the treatment. The next few questions are about your own experience.

65. Have you changed your sexual activity since you have had your heart transplant?

(CIRCLE ONE)

YES 01

NO ..... 02 **(GO TO Q.68)** 21 22

66. Is this change related to either your disease or the treatment?

(CIRCLE ONE)

YES 01

NO 02 23 24

67. Is your current sexual activity **MORE THAN OR LESS THAN** it was before you had your heart transplant?

(CIRCLE ONE)

MORE 01

LESS 02

25 26

68. Do you think your sexual desire has increased, decreased, or remained the same since you received your heart transplant?

(CIRCLE ONE)

INCREASED 01

DECREASED 02

REMAINED THE SAME 03

27 28

69. How satisfied are you with your sexual relationship(s) now?

(CIRCLE ONE)

COMPLETELY SATISFIED 01

VERY SATISFIED 02

SATISFIED 03

NEUTRAL 04

DISSATISFIED 05

VERY DISSATISFIED 06

COMPLETELY DISSATISFIED 07

29 30

70. How satisfied were you with your sexual relationship(s) before you had your heart transplant?

(CIRCLE ONE)

COMPLETELY SATISFIED	01
VERY SATISFIED	02
SATISFIED	03
NEUTRAL	04
DISSATISFIED	05
VERY DISSATISFIED	06
COMPLETELY DISSATISFIED	07

31 32

71. If there has been a change in your satisfaction with your sexual relationship(s) since the heart transplant, has this change been...

(CIRCLE ONE)

A GREAT PROBLEM	01
SOMEWHAT OF A PROBLEM	02
A SMALL PROBLEM, OR	03
NO PROBLEM AT ALL?	04
NO CHANGE	05

33 34

FAMILY AND SOCIAL RELATIONS

Next there are a few questions about your family, social relations and social activities.

72. Do you have any relatives living **OUTSIDE** your household?

(CIRCLE YES OR NO FOR EACH PERSON)

	YES	NO	
A. FATHER	01	02	35 36
B. MOTHER	01	02	— —
C. SPOUSE'S PARENTS	01	02	39 40
D. OWN CHILDREN	01	02	— —
E. OTHER RELATIVES	01	02	43 44

(IF "NO" to A through E, GO TO Q.75)

73. Do any of **these relatives** live within an hour's travel from your home?

(CIRCLE ONE)

YES 01

NO 02 45 46

74. Do any of **these relatives** help you (or your spouse) in your home (for example, housekeeping, shopping, child care)?

(CIRCLE ONE)

YES 01

NO 02 47 48

75. About how many families in your neighborhood are you well enough acquainted with that you visit each other in your homes?

_____ FAMILIES 49 50

76. About how many **CLOSE** friends and relatives do you have--people you feel at ease with and can talk with about what is on your mind?

_____ CLOSE FRIENDS 51 52

77. In general, how well are you getting along with other people these days?

(CIRCLE ONE)

BETTER THAN USUAL 01

ABOUT THE SAME 02

NOT AS WELL AS USUAL 03

78. Over a year's time, about how often do you get together with friends or relatives, like going out together or visiting in each other's homes?

(CIRCLE ONE)

EVERY DAY 01

SEVERAL DAYS A WEEK 02

ABOUT ONCE A WEEK 03

2 OR 3 TIMES A MONTH 04

ABOUT ONCE A MONTH 05

5 TO 10 TIMES A YEAR 06

LESS THAN 5 TIMES A YEAR 07

Questions 79 through 83 ask about your social activities during the **PAST MONTH.** If you were not living at home the last 30 days, please answer for the most recent month you were at home.

79. During the **PAST MONTH,** about how often have you had friends over to your home? *(Do Not Count Relatives.)*

(CIRCLE ONE)

EVERY DAY 01

SEVERAL DAYS A WEEK 02

ABOUT ONCE A WEEK 03

2 OR 3 TIMES IN PAST MONTH 04

ONCE IN PAST MONTH 05

NOT AT ALL IN PAST MONTH 06

80. About how often have you visited with friends in **THEIR** homes during the **PAST MONTH?** *(Do Not Count Relatives.)*

(CIRCLE ONE)

EVERY DAY 01
SEVERAL DAYS A WEEK 02
ABOUT ONCE A WEEK 03
2 OR 3 TIMES IN PAST MONTH 04
ONCE IN PAST MONTH 05
NOT AT ALL IN PAST MONTH 06

59 60

81. About how often were you on the telephone with close friends or relatives during the **PAST MONTH?**

(CIRCLE ONE)

EVERY DAY 01
SEVERAL TIMES A WEEK 02
ABOUT ONCE A WEEK 03
2 OR 3 TIMES IN THE PAST MONTH 04
ONCE IN PAST MONTH 05
NOT AT ALL IN THE PAST MONTH 06

61 62

82. About how often did you write a letter to a friend or relative during the **PAST MONTH?**

(CIRCLE ONE)

EVERY DAY 01
SEVERAL TIMES A WEEK 02
ABOUT ONCE A WEEK 03
2 OR 3 TIMES IN PAST MONTH 04
ONCE IN PAST MONTH 05
NOT AT ALL IN PAST MONTH 06

63 64

83. How often have you attended a religious service during the **PAST MONTH?**

(CIRCLE ONE)

EVERY DAY	01
MORE THAN ONCE A WEEK	02
ONCE A WEEK	03
2 OR 3 TIMES IN PAST MONTH	04
ONCE IN PAST MONTH	05
NOT AT ALL IN PAST MONTH	06

65 66

84. About how many voluntary groups or organizations do you belong to—like church groups, clubs or lodges, parent groups, etc.?

_____ GROUPS OR ORGANIZATIONS
(If "0", GO TO Q.86)

67 68

85. How active are you in the affairs of these groups or clubs? *(If you belong to a large number, just consider those you feel closest to.)*

(CIRCLE ONE)

VERY ACTIVE, ATTEND MOST MEETINGS	01
FAIRLY ACTIVE, ATTEND FAIRLY OFTEN	02
NOT ACTIVE, BELONG BUT HARDLY EVER GO	03

69 70

We would like to get some idea of how a recipient's heart transplant affects his/her family life. The following questions concern your immediate family--that is, those with whom you live and/or have the most contact.

86. All families are different--some are very close and others are not. Would you say the people in your immediate family are...

(CIRCLE ONE)

VERY CLOSE 01
PRETTY CLOSE 02
SOMEWHAT CLOSE, OR 03
NOT AT ALL CLOSE TO EACH OTHER? 04

87. How well do the people in your family get along together at home?

(CIRCLE ONE)

VERY WELL 01
PRETTY WELL 02
NOT SO WELL 03
NOT AT ALL WELL 04

88. How satisfied are you with your relations with your children?

(CIRCLE ONE)

VERY SATISFIED 01
SOMEWHAT SATISFIED 02
NEITHER SATISFIED NOR DISSATISFIED 03
SOMEWHAT DISSATISFIED 04
VERY DISSATISFIED 05
HAVE NO CHILDREN 06

71 72

78 2 0 6 80

(Dup 1-6)

8

9 10

89. How often are there arguments in your family these days?

(CIRCLE ONE)

ALMOST CONSTANTLY 01

OFTEN 02

ONCE IN A WHILE 03

NEVER 04

11 12

90. When a problem comes up in the family, are the people in your immediate family...

(CIRCLE ONE)

VERY WILLING TO HELP OUT 01

SOMEWHAT WILLING 02

A LITTLE WILLING, OR 03

NOT AT ALL WILLING TO HELP OUT? 04

13 14

91. How often does your immediate family do things together?

(CIRCLE ONE)

VERY OFTEN 01

SOMETIMES 02

RARELY 03

NEVER 04

15 16

92. When you first found out that you needed a heart transplant, were you and your family...

(CIRCLE ONE)

EXTREMELY WORRIED 01

SOMEWHAT WORRIED 02

A LITTLE WORRIED, OR 03

NOT AT ALL WORRIED? 04

17 18

93. How would you characterize your family while you were sick?

(CIRCLE ONE)

VERY TENSE AND NERVOUS 01

SOMEWHAT TENSE 02

A LITTLE TENSE 03

NOT AT ALL TENSE OR NERVOUS 04

19 20

94. How upset or disturbed do you feel your family has been by this disease?

(CIRCLE ONE)

VERY UPSET 01

SOMEWHAT UPSET 02

A LITTLE UPSET 03

NOT AT ALL UPSET 04

21 22

95. Some heart transplant recipients feel that their condition is very demanding of their family's time and energy, while others do not feel this way. Would you say your heart transplant has taken...

(CIRCLE ONE)

A LOT OF YOUR FAMILY'S TIME AND ENERGY 01

SOME OF THEIR TIME AND ENERGY, OR 02

A LITTLE OF THEIR TIME AND ENERGY? 03

23 24

96. How often have you felt that your heart transplant has interfered with the family routine at home?

(CIRCLE ONE)

OFTEN 01

SOMETIMES 02

RARELY 03

NEVER 04

25 26

97. Sometimes families resent it when someone in the family can't carry out their normal activities or if they need extra help. Do you feel your transplant has caused any resentment in your family?

(CIRCLE ONE)

YES 01

NO ..... 02 — — 27 28

98. How much would you say the following people have had to give up because of your heart transplant?

(CIRCLE ONE RESPONSE FOR EACH PERSON)

	VERY MUCH	SOME-WHAT	A LITTLE	NOT AT ALL	DOES NOT APPLY	
A. YOURSELF	01	02	03	04	--	— — 29 30
B. YOUR SPOUSE	01	02	03	04	05	— —
C. YOUR CHILDREN	01	02	03	04	05	— — 33 34

99. How well do you think your family understands how you feel about your heart transplant?

(CIRCLE ONE)

VERY WELL 01

SOMEWHAT WELL ..... 02 — — 35 36

NOT VERY WELL 03

100. After having major surgery, people often report that their families watch them too carefully and don't want them to return to all their normal activities, even though the person wants to. Would you say this has been true for you...

(CIRCLE ONE)

OFTEN 01

SOMETIMES, OR ..... 02 — — 37 38

NEVER? 03

101. How much does your family talk about your transplant?

(CIRCLE ONE)

VERY OFTEN 01

SOMETIMES 02

NEVER 03

39 40

102. How much worry would you say the transplant causes your family now?

(CIRCLE ONE)

GREAT AMOUNT OF WORRY 01

SOME WORRY 02

A SMALL AMOUNT OF WORRY 03

NO WORRY 04

41 42

103. In terms of other problems you and your family have faced, has your heart transplant been...

(CIRCLE ONE)

A VERY GREAT PROBLEM 01

SOMEWHAT OF A PROBLEM 02

A SMALL PROBLEM, OR 03

NO PROBLEM AT ALL? 04

43 44

104. Do you think that your heart transplant in any way brought the family closer together or in any way drew the family apart?

(CIRCLE ONE)

BROUGHT CLOSER TOGETHER 01

DREW FAMILY APART 02

NEITHER 03

45 46

105. Do you know any other heart transplant recipients?

(CIRCLE ONE)

YES 01

NO 02 47 48

106. **IF YES,** in comparison to families of other heart transplant patients, do you feel your family has been more helpful, less helpful, or about average?

(CIRCLE ONE)

MORE HELPFUL 01

LESS HELPFUL 02

ABOUT AVERAGE 03 49 50

I DON'T KNOW 04

IF MARRIED, ANSWER QUESTIONS 107-113

IF DIVORCED, ANSWER QUESTIONS 114-117

IF SINGLE OR WIDOWED, GO TO Q. 118

107. How long have you been married to your current spouse?

_____ YEARS 51 52

108. Have you remarried since your heart transplant?

(CIRCLE ONE)

YES 01

NO 02 53 54

109. Do you think that your heart transplant places a strain on your marriage?

(CIRCLE ONE)

YES 01

NO ..... 02 — 55 56

110. Do you think your spouse is very understanding or could be more understanding about your heart condition?

(CIRCLE ONE)

VERY UNDERSTANDING 01

COULD BE MORE UNDERSTANDING ..... 02 — 57 58

111. Some people say that when they're sick they feel rejected by their spouses. Would you say you feel this way often, sometimes, or never?

(CIRCLE ONE)

OFTEN 01

SOMETIMES ..... 02 — 59 60

NEVER 03

112. How has your heart transplant affected your relationship with your spouse? Do you feel..

(CIRCLE ONE)

CLOSER 01

ABOUT THE SAME, OR ..... 02 — 61 62

LESS CLOSE? 03

113. How satisfied are you with your relationship with your spouse?

(CIRCLE ONE)

VERY SATISFIED 01

SOMEWHAT SATISFIED 02

NEITHER SATISFIED NOR DISSATISFIED 03

SOMEWHAT DISSATISFIED 04

VERY DISSATISFIED 05

MARRIED PATIENTS NOW GO TO EMPLOYMENT SECTION, Q.118

114. How long have you been (divorced/separated)?

_____ YEARS

115. How long were you married and living together? *(If you have been married more than once, we are interested in the length of the most recent marriage.)*

_____ YEARS

116. Do you think the fact that you had a heart transplant strained your marriage?

(CIRCLE ONE)

YES..... 01

NO 02

NOT MARRIED AT TIME OF TRANSPLANT 03

117. **IF YES,** would you say that your (divorce/separation) was a **DIRECT** result of your need for a heart transplant?

(CIRCLE ONE)

YES..... 01

NO 02

2 0 7

EMPLOYMENT

Now we would like you to answer a few questions about your past and current work activities. We realize that your status as a heart transplant recipient may have prevented you from finding or holding a job although you may be willing and able to work.

118. We are interested in your work history; that is, the jobs you have had, the kind of work you have done, when the job began and ended, as well as your rate of pay. PLEASE FILL IN THE TABLE ON THE FOLLOWING PAGE, BEGINNING WITH THE JOB YOU HAD **FIVE YEARS PRIOR** TO YOUR TRANSPLANT AND **ENDING WITH YOUR CURRENT EMPLOYMENT.** Below, each of these items is described to better enable you to understand what we are looking for.

A. **OCCUPATION** - What kind of work have you done? For example, have you been an electrical engineer, a typist, school teacher, plumber, or what?

B. **KIND OF BUSINESS** - What kind of business or industry did you work for? For example, did you work for a TV and radio manufacturer, a public or private school system, a retail shoe store, farm, or what?

C. **SELF-EMPLOYED** - Are you self-employed or do you work for someone else?

D. **DATE YOU BEGAN JOB** - Please indicate the month and year you began each job; for example, November, 1978.

E. **DATE JOB ENDED** - Please indicate the month and year each job ended; for example, October, 1980.

F. **REASON JOB ENDED** - Please note whether or not the reason you quit or left each job was health-related.

G. **HOURS WORKED** - How many hours per week did you usually work at each job? Note the number of hours you were actually on the job each week.

H. **WEEKS WORKED** - How many weeks per year did you work at each job? If you did not work an entire year at a given job, indicate how many weeks per year you would have worked had you stayed on the job.

I. **RATE OF PAY** - Here we are interested in how much you earned or were paid before taxes on each job. Be sure to note whether the dollar amount was HOURLY, WEEKLY, MONTHLY, OR YEARLY. If you worked at one job for several years, please indicate your final salary.

WORK HISTORY

(COMPLETE ACCORDING TO THE INSTRUCTIONS ON THE PRECEDING PAGE)

	A	B	C	D	E	F	G	H	I
	OCCUPATION	KIND OF BUSINESS	SELF-EMPLOYED YES NO	DATE YOU BEGAN JOB MO YR	DATE JOB ENDED	REASON JOB ENDED HEALTH RELATED OTHER	ANNUAL RATE OF PAY	NO HOURS WORKED PER WEEK	NO WEEKS WORKED PER YEAR
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									
11									
12									
13									
14									
15									

119. Since you finished your formal schooling, that is high school, college, or trade school, approximately how many years have you worked either full-time or part-time?

(Dup 1-6)

_____ YEARS

7 8

120. What was your work activity or employment status during the **YEAR PRIOR** to your heart transplant?

(CIRCLE ONE)

EMPLOYED FULL-TIME 01

EMPLOYED PART-TIME 02

EMPLOYED BUT TEMPORARILY LAID OFF ... 03 **(GO TO Q.124)**

UNEMPLOYED, LOOKING FOR WORK ..... 04 **(GO TO Q.124)**

UNEMPLOYED, NOT LOOKING FOR WORK .... 05 **(GO TO Q.124)**

9 10

UNABLE TO WORK BECAUSE OF HEALTH (DISABLED) ..... 06 **(GO TO Q.124)**

HOMEMAKER ..... 07 **(GO TO Q.124)**

STUDENT (FULL-TIME) ..... 08 **(GO TO Q.124)**

RETIRED ..... 09 **(GO TO Q.124)**

OTHER (SPECIFY) _____ 10

121. How often did you do the following kinds of things **on the job?** Did you have to do these activities a lot, sometimes, or rarely?

(CIRCLE ONE RESPONSE FOR EACH ACTIVITY)

	OFTEN	SOME-TIMES	RARELY	
A. WALK	01	02	03	11 12
B. USE STAIRS OR INCLINES	01	02	03	— —
C. STAND FOR LONG PERIODS	01	02	03	15 16
D. SIT FOR LONG PERIODS	01	02	03	— —
E. STOOP, CROUCH, OR KNEEL	01	02	03	19 20
F. REACH	01	02	03	— —
G. USE FINGERS TO GRASP OR HANDLE	01	02	03	23 24
H. USE YOUR EYES FOR INSPECTION OF THINGS	01	02	03	— —
I. USE YOUR EYES FOR READING	01	02	03	— —
J. LIFT OR CARRY WEIGHTS UP TO 10 POUNDS	01	02	03	29 30
K. LIFT OR CARRY WEIGHTS UP TO 25 POUNDS	01	02	03	— —
L. LIFT OR CARRY WEIGHTS UP TO 50 POUNDS	01	02	03	33 34

122. Did the last employer you had before your transplant do anything special for you because of your heart condition to make it easier for you to work at your job?

(CIRCLE ONE)

YES 01

NO ..... 02 — — 35 36

NO, HAD NO HEALTH PROBLEM AT THE TIME 03

123. **IF YES,** what did he/she do?

(CIRCLE YES OR NO FOR EACH ITEM)

	YES	NO	
A. GOT SOMEONE TO HELP YOU	01	02	37 38
B. CHANGED JOBS (TASKS) TO SOMETHING YOU COULD DO	01	02	— —
C. HELPED YOU LEARN NEW SKILLS	01	02	41 42
D. SHORTENED WORK DAY	01	02	— —
E. ALLOWED FLEXIBLE SCHEDULE	01	02	45 46
F. ALLOWED MORE BREAKS AND REST PERIODS	01	02	— —
G. GOT SPECIAL EQUIPMENT FOR THE JOB	01	02	49 50
H. ARRANGED SPECIAL TRANSPORTATION	01	02	— —
I. EXTENDED SICK LEAVE	01	02	— —
J. OTHER (SPECIFY) _____	01	02	55 56

124. Does your health keep you from working on a job for pay now?

(CIRCLE ONE)

YES	01	
NO	02	57 58

125. Are you limited in the **KIND** of work for pay you can do because of your health?

(CIRCLE ONE)

YES	01	
NO	02	59 60

126. Are you limited in the **AMOUNT** of work for pay you can do because of your health?

(CIRCLE ONE)

YES 01

NO ..... 02 — 61 62

127. Are you **NOW ABLE** to work for pay full-time, part-time, or not at all?

(CIRCLE ONE)

FULL-TIME 01

PART-TIME ..... 02 — 63 64

NOT AT ALL ..... 03 **(GO TO Q.134)**

128. Are you **NOW ABLE** to work for pay regularly or can you work only occasionally or irregularly?

(CIRCLE ONE)

REGULARLY 01

OCCASIONALLY OR IRREGULARLY ..... 02 — 65 66

129. What is your **CURRENT** work activity or employment status?

(CIRCLE ONE)

EMPLOYED FULL-TIME	01	
EMPLOYED PART-TIME	02	
EMPLOYED BUT TEMPORARILY LAID OFF	03	**(GO TO Q.134)**
UNEMPLOYED, LOOKING FOR WORK	04	**(GO TO Q.134)**
UNEMPLOYED, NOT LOOKING FOR WORK	05	**(GO TO Q.134)**
UNABLE TO WORK BECAUSE OF HEALTH (DISABLED)	06	**(GO TO Q.134)**
HOMEMAKER	07	**(GO TO Q.134)**
STUDENT (FULL-TIME)	08	**(GO TO Q.134)**
RETIRED	09	**(GO TO Q.134)**
OTHER (SPECIFY) _____	10	

130. How satisfied are you with your present job?

(CIRCLE ONE)

COMPLETELY SATISFIED	01
VERY SATISFIED	02
SATISFIED	03
NEUTRAL	04
DISSATISFIED	05
VERY DISSATISFIED	06
COMPLETELY DISSATISFIED	07
NOT CURRENTLY EMPLOYED	08

131. Do you currently like work more, about the same or less than before you had your heart transplant?

(CIRCLE ONE)

MORE 01

ABOUT THE SAME 02

LESS 03

71 72

132. Has your current employer done anything special for you now because of your heart problem to make it easier for you to work at your job?

(CIRCLE ONE)

YES 01

NO 02

73 74

2 0 8

78 80

133. **IF YES,** what has he/she done?

(CIRCLE YES OR NO FOR EACH ITEM)

(Dup 1-6)

	YES	NO	
A. GOT SOMEONE TO HELP YOU	01	02	7 8
B. MADE WORK A LITTLE EASIER OR CHANGED JOB (TASKS) TO SOMETHING YOU COULD DO	01	02	— —
C. HELPED YOU LEARN NEW SKILLS	01	02	11 12
D. SHORTENED WORK DAY	01	02	— —
E. CHANGED TIME YOU CAME TO AND LEFT WORK	01	02	15 16
F. ALLOWED ME MORE BREAKS AND REST PERIODS	01	02	— —
G. GOT SPECIAL EQUIPMENT FOR THE JOB	01	02	19 20
H. ARRANGED SPECIAL TRANSPORTATION	01	02	— —
I. OTHER (SPECIFY) _____	01	02	— —
J. OTHER (SPECIFY) _____	01	02	25 26

HEALTH

Now we would like to know a little more about your health.

134. How would you rate your overall health at the present time?

(CIRCLE ONE)

EXCELLENT 01

GOOD 02

FAIR 03

POOR 04

27 28

135. Is your health now better, about the same, or worse than it was five years ago?

(CIRCLE ONE)

BETTER 01

ABOUT THE SAME 02

WORSE 03

29 30

136. Is your health now better, about the same, or worse than it was **THE YEAR BEFORE** you had your heart transplant?

(CIRCLE ONE)

BETTER 01

ABOUT THE SAME 02

WORSE 03

31 32

137. **IN THE PAST YEAR,** how many times have you been in the hospital **OVERNIGHT** for any condition **OTHER THAN IN THE HOSPITAL WHERE YOU RECEIVED YOUR HEART TRANSPLANT?**

NUMBER OF TIMES _____

(If "0", GO TO Q.139)

33 34

138. What is the total number of **NIGHTS** you have spent in these **OTHER** hospitals in the **LAST YEAR?**

NUMBER OF NIGHTS _____ 35 36 37

139. During the **PAST 6 MONTHS,** have you stayed home in bed because of any illness or injury?

(CIRCLE ONE)

YES 01

NO 02 38 39

140. **IF YES,** during this 6 month period, how many **DAYS** did you stay in bed all or most of the day?

NUMBER OF DAYS _____ 40 41 42

141. In the **LAST MONTH,** how many nights did you spend in **ANY** hospital?

NUMBER OF NIGHTS _____ 43 44

142. How many times in the **LAST MONTH** have you seen a doctor for **ANY CONDITION?**

NUMBER OF TIMES

A. CARDIOLOGIST ..... _____ 45 46

B. SURGEON ..... _____ 47 48

C. FAMILY PHYSICIAN ..... _____ 49 50

D. OTHER ..... _____ 51 52

143. Below is a list of symptoms. Just **before you had your heart transplant,** how often did you have each of the following symptoms? Did you have them very often, sometimes, rarely, or never?

(CIRCLE ONE RESPONSE FOR EACH SYMPTOM)

	VERY OFTEN	SOME-TIMES	RARELY	NEVER	
A. PAIN	01	02	03	04	— —
B. TIRING EASILY, NO ENERGY	01	02	03	04	— —
C. WEAKNESS, LACK OF STRENGTH	01	02	03	04	— —
D. ACHES, SWELLING, SICK FEELING	01	02	03	04	— —
E. FAINTING SPELLS, DIZZINESS	01	02	03	04	— —
F. NERVOUSNESS, TENSION, ANXIETY	01	02	03	04	— —
G. SHORTNESS OF BREATH, TROUBLE BREATHING	01	02	03	04	— —
H. DEPRESSION	01	02	03	04	— —

2 0 9

144. **Since you received your heart transplant,** how often have you had each of the following symptoms? Have you had them very often, sometimes, rarely, or never?

(CIRCLE ONE RESPONSE FOR EACH SYMPTOM)

(Dup 1-6)

	VERY OFTEN	SOME-TIMES	RARELY	NEVER	
A. PAIN	01	02	03	04	7 8
B. TIRING EASILY, NO ENERGY	01	02	03	04	9 10
C. WEAKNESS, LACK OF STRENGTH	01	02	03	04	11 12
D. ACHES, SWELLING, SICK FEELING	01	02	03	04	13 14
E. FAINTING SPELLS, DIZZINESS	01	02	03	04	15 16
F. NERVOUSNESS, TENSION, ANXIETY	01	02	03	04	17 18
G. SHORTNESS OF BREATH, TROUBLE BREATHING	01	02	03	04	19 20
H. DEPRESSION	01	02	03	04	21 22

145. This question may be a little harder to answer and will require careful thought. Let us speculate for a moment. **Suppose** you could choose your length of life and state of health and were given the following choice. Consider your present level of health, in other words any pain, suffering, or immobility which you may experience because of your health. Suppose instead that you could have good health and avoid this pain and suffering, but at the cost of having a shorter life. Specifically, if you were able to give up a certain number of **DAYS OR WEEKS EACH YEAR** in return for **GOOD HEALTH** during the rest of the year, how much time, if any, would you be willing to give up?

NUMBER OF DAYS _____

or

NUMBER OF WEEKS _____

23 24 25

LIFESTYLE

The following questions concern your diet and exercise.

146. Which of the following diets, if any, are you currently on?

(CIRCLE YES OR NO FOR EACH ITEM)

	YES	NO	
A. WEIGHT REDUCING	01	02	26 27
B. LOW CHOLESTEROL	01	02	— —
C. LOW SALT	01	02	— —
D. DIABETIC	01	02	32 33

147. How often, if at all, do you follow your diet as prescribed by your doctor?

(CIRCLE ONE)

ALWAYS	01	
MOST OF THE TIME	02	
SOME OF THE TIME	03	34 35
NEVER	04	
NOT ON A SPECIAL DIET	05	

148. How often, if at all, is your weight gain between your six-month checkups higher than it should be?

(CIRCLE ONE)

FREQUENTLY	01	
OCCASIONALLY	02	
RARELY	03	36 37
NEVER	04	
HAVE NOT HAD A SIX-MONTH CHECKUP	05	

149. How often, if at all, do you take your drugs as prescribed by your doctor?

(CIRCLE ONE)

ALWAYS	01
MOST OF THE TIME	02
SOME OF THE TIME	03
NEVER	04

38 39

Next there are some questions about your current level of physical activity. Please regard the examples given as general guidelines relative to your physical condition. For example, if bowling is a **strenuous** activity **for you,** please count it as such.

150. During the past **MONTH,** about how many hours **PER WEEK** did you spend in **LIGHT** activities like these:

- STANDING OR WALKING SLOWLY
- BOWLING
- FISHING QUIETLY
- PLAYING MUSICAL INSTRUMENT
- MOWING THE LAWN WITH POWER MOWER
- OTHER LIGHT ACTIVITES?

(CIRCLE ONE)

NO HOURS PER WEEK	01
5 HOURS OR LESS	02
6 TO 15	03
16 TO 25	04
26 TO 35	05
36 HOURS OR MORE	06

40 41

151. During the past **MONTH,** about how many hours **PER WEEK** did you spend in **MEDIUM** activities like these:

- BICYCLING
- PLAYING GOLF
- DANCING
- CANOEING (NOT WHITE WATER)
- DIGGING OR GARDENING
- DOING CARPENTRY
- SWIMMING SLOWLY
- OTHER MEDIUM ACTIVITIES?

(CIRCLE ONE)

NO HOURS PER WEEK	01
1 HOUR	02
2 TO 5	03
6 TO 10	04
11 TO 15	05
16 HOURS OR MORE	06

42 43

152. During the past **MONTH,** about how many hours **PER WEEK** did you spend in **STRENUOUS** activities like these:

- CARRYING HEAVY WEIGHTS (80 LBS. OR MORE)
- SHOVELING HEAVY LOADS
- JOGGING OR RUNNING FAST
- SKIING
- PLAYING FULL COURT BASKETBALL
- PLAYING HANDBALL OR SQUASH
- PLAYING TOUCH FOOTBALL
- OTHER STRENUOUS (HEAVY) ACTIVITIES?

(CIRCLE ONE)

NO HOURS PER WEEK	01
1 HOUR	02
2 TO 5	03
6 TO 10	04
11 TO 15	05
16 HOURS OR MORE	06

44 45

153. Which statement describes you best?

(CIRCLE ONE)

NOT VERY ACTIVE, SITTING AND WALKING MOSTLY 01

A WEEKEND OR VACATION EXERCISER 02

PHYSICALLY ACTIVE AT LEAST 1-2 TIMES DURING THE WEEK 03

PHYSICALLY ACTIVE 3 OR MORE TIMES DURING THE WEEK 04

154. Which of the following statements best describes your life during the **PAST MONTH?**

(CIRCLE ONE)

WELL AND DOING MOST THINGS I DID BEFORE MY ILLNESS 01

WELL BUT NOT PERFORMING MANY CUSTOMARY ACTIVITIES 02

UP MOST OF THE DAY BUT QUITE RESTRICTED ACTIVITY 03

CONFINED TO A WHEELCHAIR WHEN OUT OF BED 04

CONFINED TO BED BUT FEELING WELL 05

CONFINED TO BED AND NOT FEELING WELL 06

PERSONAL ADJUSTMENT

155. Because of your heart condition, do you think you need...

(CIRCLE ONE)

A LOT OF EXTRA HELP TO GET THINGS DONE 01

SOME EXTRA HELP TO GET THINGS DONE 02

A LITTLE EXTRA HELP, OR 03

NO MORE HELP THAN ANY HEALTHY PERSON? 04

50 51

156. Because of your heart condition, do you feel you...

(CIRCLE ONE)

ARE MORE DEPENDENT ON OTHERS FOR HELP THAN YOU WOULD LIKE TO BE, OR 01

THAT YOU WOULD LIKE TO HAVE SOMEONE YOU COULD DEPEND ON MORE, OR 02

NEITHER? ..... 03 **(GO TO Q. 158)**

52 53

157. How much of a problem is your dependence upon others since you had your heart transplant?

(CIRCLE ONE)

A GREAT PROBLEM 01

SOMEWHAT OF A PROBLEM 02

A SMALL PROBLEM. 03

NO PROBLEM 04

54 55

158. How independent do you feel you are now with regard to managing your life?

(CIRCLE ONE)

VERY INDEPENDENT 01

PRETTY INDEPENDENT 02

NOT VERY INDEPENDENT 03

NOT AT ALL INDEPENDENT 04

159. How worried were you about your finances **at the time of the transplant?**

(CIRCLE ONE)

EXTREMELY WORRIED 01

MODERATELY WORRIED 02

A LITTLE WORRIED 03

NOT AT ALL WORRIED 04

160. How worried are you about your finances **now?**

(CIRCLE ONE)

EXTREMELY WORRIED 01

MODERATELY WORRIED 02

A LITTLE WORRIED 03

NOT AT ALL WORRIED 04

161. If you were to compare yourself now to the time before you had your heart transplant, do you think you are generally...

(CIRCLE ONE)

HAPPIER THAN YOU WERE BEFORE YOU HAD A TRANSPLANT 01

LESS HAPPY, OR 02

ABOUT AS HAPPY AS YOU WERE BEFORE? 03

CAN'T REMEMBER HOW YOU FELT 04

This study is also interested in learning about the way you handle your health problems and the way you feel about your heart condition. Please read each statement and circle the response which best describes you.

162. I think about my heart condition all of the time.

(CIRCLE ONE)

STRONGLY AGREE 01
AGREE 02
NOT SURE 03
DISAGREE 04
STRONGLY DISAGREE 05

64 65

163. I feel like giving in to this illness.

(CIRCLE ONE)

STRONGLY AGREE 01
AGREE 02
NOT SURE 03
DISAGREE 04
STRONGLY DISAGREE 05

66 67

164. I have some tasks to accomplish in my life that are important to me.

(CIRCLE ONE)

STRONGLY AGREE 01
AGREE 02
NOT SURE 03
DISAGREE 04
STRONGLY DISAGREE 05

68 69

165. I have done most of the things I wanted to in my life.

(CIRCLE ONE)

STRONGLY AGREE 01
AGREE 02
NOT SURE 03
DISAGREE 04
STRONGLY DISAGREE 05

70 71

166. I am important to someone.

(CIRCLE ONE)

STRONGLY AGREE 01
AGREE 02
NOT SURE 03
DISAGREE 04
STRONGLY DISAGREE 05

72 73

2 1 0
78 80

167. There are people who depend on me.

(CIRCLE ONE)

(Dup 1-6)

STRONGLY AGREE 01
AGREE 02
NOT SURE 03
DISAGREE 04
STRONGLY DISAGREE 05

— — 8

168. My religious or personal spiritual beliefs give meaning to my life.

(CIRCLE ONE)

STRONGLY AGREE 01
AGREE 02
NOT SURE 03
DISAGREE 04
STRONGLY DISAGREE 05

— — 9 10

169. My life is empty and has no meaning.

(CIRCLE ONE)

STRONGLY AGREE 01
AGREE 02
NOT SURE 03
DISAGREE 04
STRONGLY DISAGREE 05

— — 11 12

170. I am determined to do everything possible to improve or recover.

(CIRCLE ONE)

STRONGLY AGREE 01
AGREE 02
NOT SURE 03
DISAGREE 04
STRONGLY DISAGREE 05

13 14

171. I have a strong will to live.

(CIRCLE ONE)

STRONGLY AGREE 01
AGREE 02
NOT SURE 03
DISAGREE 04
STRONGLY DISAGREE 05

15 16

172. It is difficult for me to accept the fact that I may die from this illness.

(CIRCLE ONE)

STRONGLY AGREE 01
AGREE 02
NOT SURE 03
DISAGREE 04
STRONGLY DISAGREE 05

17 18

173. I find it best not think too much about dying.

(CIRCLE ONE)

STRONGLY AGREE	01
AGREE	02
NOT SURE	03
DISAGREE	04
STRONGLY DISAGREE	05

19 20

174. In some form I believe that there is life after death.

(CIRCLE ONE)

STRONGLY AGREE	01
AGREE	02
NOT SURE	03
DISAGREE	04
STRONGLY DISAGREE	05

21 22

175. I have a religious or spiritual perspective on death.

(CIRCLE ONE)

STRONGLY AGREE	01
AGREE	02
NOT SURE	03
DISAGREE	04
STRONGLY DISAGREE	05

23 24

176. A person should have the right to decide to die.

(CIRCLE ONE)

STRONGLY AGREE	01
AGREE	02
NOT SURE	03
DISAGREE	04
STRONGLY DISAGREE	05

177. When I think about my own death I get very angry.

(CIRCLE ONE)

STRONGLY AGREE	01
AGREE	02
NOT SURE	03
DISAGREE	04
STRONGLY DISAGREE	05

178. If I work at it, I can usually get what I want.

(CIRCLE ONE)

STRONGLY AGREE	01
AGREE	02
NOT SURE	03
DISAGREE	04
STRONGLY DISAGREE	05

179. Almost everything I do is determined by what other people want me to do.

(CIRCLE ONE)

STRONGLY AGREE 01
AGREE 02
NOT SURE 03
DISAGREE 04
STRONGLY DISAGREE 05

31 32

180. I am usually able to influence others.

(CIRCLE ONE)

STRONGLY AGREE 01
AGREE 02
NOT SURE 03
DISAGREE 04
STRONGLY DISAGREE 05

33 34

181. I often run into problems that I can't solve.

(CIRCLE ONE)

STRONGLY AGREE 01
AGREE 02
NOT SURE 03
DISAGREE 04
STRONGLY DISAGREE 05

35 36

182. I feel that I usually succeed in solving my problems.

(CIRCLE ONE)

STRONGLY AGREE 01

AGREE 02

NOT SURE 03

DISAGREE 04

STRONGLY DISAGREE 05

183. During the past month, I have often been in unpleasant situations that I have felt helpless to do anything about.

(CIRCLE ONE)

STRONGLY AGREE 01

AGREE 02

NOT SURE 03

DISAGREE 04

STRONGLY DISAGREE 05

184. I am usually able to give what I like to the people closest to me.

(CIRCLE ONE)

STRONGLY AGREE 01

AGREE 02

NOT SURE 03

DISAGREE 04

STRONGLY DISAGREE 05

185. During the past month, there has always been someone available when I wanted to talk.

(CIRCLE ONE)

STRONGLY AGREE 01
AGREE 02
NOT SURE 03
DISAGREE 04
STRONGLY DISAGREE 05

186. During the past year when I was unable to get to the doctor on my own, there was someone to help me.

(CIRCLE ONE)

STRONGLY AGREE 01
AGREE 02
NOT SURE 03
DISAGREE 04
STRONGLY DISAGREE 05

187. I get a lot of support from friends and family on following the directions I receive from my doctor or nurse.

(CIRCLE ONE)

STRONGLY AGREE 01
AGREE 02
NOT SURE 03
DISAGREE 04
STRONGLY DISAGREE 05

188. During the past month, I often took time to do things I enjoy.

(CIRCLE ONE)

STRONGLY AGREE 01

AGREE 02

NOT SURE 03

DISAGREE 04

STRONGLY DISAGREE 05

SOCIAL SERVICES

In the next group of questions we will be asking about your experiences with government programs that provide cash benefits or other services.

189. Have you **EVER** applied for any of the following kinds of benefits?

(CIRCLE YES OR NO FOR EACH BENEFIT)

(Dup 1-6)

	YES	NO	
A. SOCIAL SECURITY RETIREMENT	01	02	— — (7–8)
B. SOCIAL SECURITY DISABILITY (GREEN CHECK)	01	02	— —
C. SOCIAL SECURITY MEDICARE	01	02	— — (11–12)
D. SOCIAL SECURITY SUPPLEMENTAL SECURITY INCOME (SSI) (GOLD CHECK)	01	02	— —
E. PUBLIC WELFARE OR ASSISTANCE	01	02	— — (15–16)
F. VETERAN'S ADMINISTRATION (VA) BENEFITS	01	02	— —
G. WORKMEN'S COMPENSATION	01	02	— — (19–20)
H. FEDERAL, STATE, OR LOCAL HOUSING SUBSIDIES	01	02	— —
I. FEDERAL FOOD STAMPS	01	02	— — (23–24)
J. MEDICAID	01	02	— —
K. STATE EMPLOYMENT SERVICE	01	02	— — (27–28)
L. PRIVATE SOCIAL SERVICES	01	02	— —
M. STATE SPONSORED REHABILITATION	01	02	— —
N. SPECIAL INCOME TAX EXEMPTION DUE TO LEGAL BLINDNESS	01	02	— — (33–34)

2 1 2 (78–80)

190. Do you **CURRENTLY** receive any of the following? For each "YES" list approximately how much you receive from each benefit per month.

(CIRCLE YES OR NO FOR EACH BENEFIT-FOR EACH YES, LIST AMOUNT)

(Dup 1-6)

	YES	NO	DOLLARS	
A. SOCIAL SECURITY RETIREMENT OR DISABILITY BENEFITS (GREEN CHECK)	01	02	$_____	— — — — 10
B. SUPPLEMENTAL SECURITY INCOME (SSI) (GOLD CHECK)	01	02	_____	— — — —
C. RAILROAD RETIREMENT BENEFITS	01	02	_____	— — — — 15 18
D. VETERANS ADMINISTRATION BENEFITS	01	02	_____	— — — —
E. UNEMPLOYMENT COMPENSATION	01	02	_____	— — — — 23 26
F. WORKMEN'S COMPENSATION	01	02	_____	— — — —
G. "AID TO FAMILIES WITH DEPENDENT CHILDREN" (AFDC) ASSISTANCE	01	02	_____	— — — — 31 34
H. PUBLIC WELFARE OR ASSISTANCE	01	02	_____	— — — —
I. CIVIL SERVICE BENEFITS	01	02	_____	— — — — 39 42
J. UNION OR EMPLOYER DISABILITY BENEFITS	01	02	_____	— — — —
K. UNION OR EMPLOYER RETIREMENT OR PENSION BENEFITS	01	02	_____	— — — —
L. ANY OTHER BENEFITS (SPECIFY) _____	01	02	_____	— — — — 51 54

191. Have you ever received any of the following rehabilitation services since you became a heart transplant **candidate?**

(CIRCLE YES OR NO FOR EACH SERVICE)

	YES	NO
A. COUNSELING AND GUIDANCE	01	02
B. PHYSICAL THERAPY	01	02
C. JOB TRAINING	01	02
D. JOB PLACEMENT	01	02
E. VOCATIONAL OR BUSINESS SCHOOL TRAINING	01	02
F. COLLEGE OR UNIVERSITY EDUCATION	01	02
G. PSYCHOTHERAPY	01	02
H. SPECIAL DEVICES (e.g. BRACE, ARTIFICIAL LIMB)	01	02
I. CANE TRAINING FOR THE BLIND	01	02

OVERVIEW

192. Thinking back over the time since you received your heart transplant, how well do you think you have adjusted to it?

(CIRCLE ONE)

VERY WELL 01

FAIRLY WELL 02

NOT TOO WELL 03

FAIRLY POORLY 04

VERY POORLY 05

2 1 3

193. Has the time since your transplant been...

(CIRCLE ONE)

(Dup 1-6)

ABOUT WHAT YOU EXPECTED 01

WORSE THAN YOU EXPECTED, OR 02

BETTER THAN YOU EXPECTED? 03

194. Thinking back over the time since you received your heart transplant, how often have you felt that it as a mistake to have a transplant?

(CIRCLE ONE)

NEVER 01

ALMOST NEVER 02

SOMETIMES 03

VERY OFTEN 04

ALWAYS 05

195. In general, do you feel that you were well informed by doctors and transplant center staff **BEFORE** the operation about the transplant procedure and recovery?

(CIRCLE ONE)

YES 01

NO 02

196. Do you think the information on transplant costs you received **PRIOR** to the transplant was accurate?

(CIRCLE ONE)

YES 01

NO 02

NO INFORMATION PROVIDED 03

TRANSPLANT COSTS, INSURANCE COVERAGE, AND FINANCIAL RESOURCES

One of the objectives of this study is to estimate the costs of heart transplantation. We are interested in the costs of both medical treatment and nonmedical items, such as travel and lodging related to your transplant. However, since we will be able--with your consent--to obtain your costs of treatment at the transplant center, the focus of the following questions will be on items not included in transplant center records. First, we would like to ask some questions about your travel and lodging expenses.

197. How far did you have to travel **ONE WAY** to get to the transplant center for the initial evaluation for your heart transplant?

APPROXIMATE NUMBER OF MILES _____ 15 16 17 18

198. After you were declared a candidate, where did you live or spend the most time during the period awaiting transplantation?

(CIRCLE ONE)

AT HOME (YOUR PERMANENT RESIDENCE) 01

IN RENTAL APARTMENT OR HOUSE 02

WITH FRIENDS OR RELATIVES NEAR TRANSPLANT CENTER 03

IN HOSPITAL NEAR HOME 04 19 20

IN TRANSPLANT CENTER HOSPITAL 05

OTHER (SPECIFY) _____ 06

OTHER (SPECIFY) _____ 07

199. If you took up lodging near the center while awaiting transplantation, what arrangements did you make for your permanent residence?

(CIRCLE ONE)

SOLD HOME 01

RENTED OUT HOME OR APARTMENT 02

LEFT OCCUPIED BY OTHER FAMILY OR FRIENDS 03

LEFT UNOCCUPIED UNTIL RETURN 04 21 22

OTHER (SPECIFY) _____ 05

DOES NOT APPLY 06

200. If you took up lodging near the center while awaiting transplantation, did your spouse or some other relative stay with you during this period?

(CIRCLE ONE)

YES, THE ENTIRE PERIOD 01

YES, MOST OF THE PERIOD 02

YES, LESS THAN HALF OF THE PERIOD 03

NO 04

DOES NOT APPLY 05

201. In the period during which you were in the hospital following your transplant, did your spouse or other relatives take up lodging near the transplant center?

(CIRCLE ONE)

YES, THE ENTIRE PERIOD 01

YES, MOST OF THE PERIOD 02

YES, LESS THAN HALF OF THE PERIOD 03

NO 04

DOES NOT APPLY 05

Next we would like to get some idea of your medical expenses that might not be reflected in your hospital records at the transplant center.

202. In the period after you were evaluated and declared a candidate, but while you were awaiting transplantation, did you stay overnight in any hospital other than the transplant center hospital?

(CIRCLE ONE)

YES 01

NO ..... 02 **(GO TO Q.205)** — — 27 28

203. How many nights did you spend in these other hospitals (other than the transplant center)?

NUMBER OF NIGHTS IN REGULAR WARD ..... _____ — — 29 31

NUMBER OF NIGHTS IN CORONARY CARE OR INTENSIVE CARE UNIT ..... _____ — — 32 34

204. If you did spend time in a hospital other than the transplant center, what were your total expenses for these stays?

TOTAL HOSPITAL EXPENSES $_____ — — — — — — 35 40

205. a) Considering **all** of your medical expenses in the period while awaiting the transplant, which of the following were payment sources and which sources paid the largest share?

(CIRCLE YES OR NO FOR EACH PAYMENT SOURCE)

	YES	NO
A. OUT OF OWN POCKET	01	02
B. PRIVATE INSURANCE	01	02
C. MEDICARE	01	02
D. MEDICAID (OR MEDI-CAL)	01	02
E. TRANSPLANT CENTER	01	02
F. DIRECT DONATIONS	01	02
G. OTHER (SPECIFY) _____	01	02
H. OTHER (SPECIFY) _____	01	02

b) Which of the above was the major source of payment:

_____
MAJOR PAYMENT SOURCE

206. Approximately what share or percentage of total medical expenses during this period did you pay out of your own pocket?

_____ %

2 1 4

207. a) Who paid for your medical expenses for the transplant operation and your stay in the hospital following the operation?

(CIRCLE YES OR NO FOR EACH PAYMENT SOURCE)

(Dup 1-6)

	YES	NO	
A. OUT OF OWN POCKET	01	02	7 8
B. PRIVATE INSURANCE	01	02	9 10
C. MEDICARE	01	02	11 12
D. MEDICAID (OR MEDI-CAL)	01	02	13 14
E. TRANSPLANT CENTER	01	02	15 16
F. DIRECT DONATIONS	01	02	17 18
G. OTHER (SPECIFY) _____	01	02	19 20
H. OTHER (SPECIFY) _____	01	02	21 22

b) Which of the above was the major source of payment:

_____
MAJOR PAYMENT SOURCE

23 24

208. Approximately what share or percentage of total medical expenses during this period did you pay out of your own pocket?

_____ %

25 26 27

209. a) Who has paid for your medical expenses in the period since your discharge from the hospital following your transplant operation?

(CIRCLE YES OR NO FOR EACH PAYMENT SOURCE)

	YES	NO	
A. OUT OF OWN POCKET	01	02	28 29
B. PRIVATE INSURANCE	01	02	30 31
C. MEDICARE	01	02	32 33
D. MEDICAID (OR MEDI-CAL)	01	02	34 35
E. TRANSPLANT CENTER	01	02	36 37
F. DIRECT DONATIONS	01	02	38 39
G. OTHER (SPECIFY) _____	01	02	40 41
H. OTHER (SPECIFY) _____	01	02	42 43

b) Which of the above was the major source of payment:

_____
MAJOR PAYMENT SOURCE

44 45

210. Approximately what share or percentage of total medical expenses during this period did you pay out of your own pocket?

_____ % 46 47 48

211. Was it necessary to do any of the following to help pay for your transplant costs?

(CIRCLE YES OR NO FOR EACH ITEM)

	YES	NO
A. SPOUSE STARTED WORKING/ RETURNED TO WORK	01	02
B. SPOUSE GOT A BETTER PAYING JOB	01	02
C. SPOUSE BEGAN WORKING LONGER HOURS	01	02
D. BORROWED MONEY FROM FRIENDS OR RELATIVES	01	02
E. MORTGAGED HOME OR OBTAINED A BANK LOAN	01	02
F. OTHER (SPECIFY) _____	01	02
G. DOES NOT APPLY	01	02

212. Are you currently paying medical bills and/or other debts associated with your heart transplant?

(CIRCLE ONE)

YES 01

NO 02

213. A. **IF YES,** how much longer do you think it will take to pay these debts?

_____ YEARS

B. **IF NO,** how long did it take you to pay these debts?

_____ *YEARS*

Next we would like to ask you about your experience in 1982 in detail.

214. In 1982 how many nights did you spend in a hospital other than the transplant center hospital?

_____ NIGHTS

2 1 5

215. What were your total medical expenses for these hospital stays?

(Dup 1-6)

TOTAL MEDICAL EXPENSES $ _____ — — — — — — 12

216. a) Who paid these expenses?

(CIRCLE YES OR NO FOR EACH PAYMENT SOURCE)

	YES	NO	
A. OUT OF OWN POCKET	01	02	13 14
B. PRIVATE INSURANCE	01	02	— —
C. MEDICARE	01	02	17 18
D. MEDICAID (OR MEDI-CAL)	01	02	— —
E. TRANSPLANT CENTER	01	02	21 22
F. DIRECT DONATIONS	01	02	— —
G. OTHER (SPECIFY) _____	01	02	— —
H. OTHER (SPECIFY) _____	01	02	27 28

b) Which of the above was the major source of payment:

_____
MAJOR PAYMENT SOURCE — — 29 30

217. Approximately what share or percentage of total medical expenses during this period did you pay out of your own pocket?

_____ % — — 31 33

218. In 1982, how many office visits to physicians did you make **OTHER THAN YOUR ROUTINE HEART-RELATED CHECKUPS WITH YOUR CARDIOLOGIST OR INTERNIST?**

NUMBER OF OFFICE VISITS _____ — — 34 36

219. What was the total expense (including office fees and diagnostic tests) associated with these visits?

TOTAL EXPENSES $ _____ — — — — — — 37 42

220. a) Who paid for these expenses?

(CIRCLE YES OR NO FOR EACH PAYMENT SOURCE)

	YES	NO
A. OUT OF OWN POCKET	01	02
B. PRIVATE INSURANCE	01	02
C. MEDICARE	01	02
D. MEDICAID (OR MEDI-CAL)	01	02
E. TRANSPLANT CENTER	01	02
F. DIRECT DONATIONS	01	02
G. OTHER (SPECIFY) _____	01	02
H. OTHER (SPECIFY) _____	01	02

b) Which of the above was the major source of payment:

_____
MAJOR PAYMENT SOURCE

221. Approximately what share or percentage of total medical expenses during this period did you pay out of your own pocket?

_____ %

222. In 1982, where did you obtain your prescribed immunosuppressive drugs (such as prednisone, Imuran, and cyclosporin-A)?

(CIRCLE YES OR NO FOR EACH SOURCE)

	YES	NO
A. RECEIVED FROM TRANSPLANT CENTER	01	02
B. GOT AT LOCAL PHARMACY	01	02
C. OTHER (SPECIFY) _____	01	02

223. What was the total expense for these drugs in 1982?

TOTAL EXPENSES $ _____

2 1 6

224. a) Who paid for these expenses?

(CIRCLE YES OR NO FOR EACH PAYMENT SOURCE)

	YES	NO	(Dup 1-6)
A. OUT OF OWN POCKET	01	02	7 8
B. PRIVATE INSURANCE	01	02	9 10
C. MEDICARE	01	02	11 12
D. MEDICAID (OR MEDI-CAL)	01	02	13 14
E. TRANSPLANT CENTER	01	02	15 16
F. DIRECT DONATIONS	01	02	17 18
G. OTHER (SPECIFY) _____	01	02	19 20
H. OTHER (SPECIFY) _____	01	02	21 22

b) Which of the above was the major source of payment:

_____
MAJOR PAYMENT SOURCE

23 24

225. Approximately what share or percentage of total medical expenses during this period did you pay out of your own pocket?

_____ %

25 26 27

226. How much did you spend on other prescription medications (such as Tagamet or Valium) or non-prescription medications in 1982?

TOTAL EXPENSES $ _____

28 29 30 31 32 33

227. What percentage of this expense was out of your own pocket?

_____ %

34 35 36

228. Do you own or rent any of the following types of medical equipment for your follow-up care?

(CIRCLE ONE RESPONSE FOR EACH ITEM)

	OWN	RENT	DON'T USE	
A. EXERCISE BICYCLE	01	02	03	37 38
B. ROWING MACHINE	01	02	03	
C. PORTABLE EKG	01	02	03	41 42
D. WHEELCHAIR	01	02	03	
E. HOSPITAL BED	01	02	03	45 46
F. OTHER (SPECIFY) _____	01	02	03	
G. OTHER (SPECIFY) _____	01	02	03	49 50

We would also like to know about your current regimen of routine care since the transplant.

229. How frequently are you scheduled to see your **CARDIOLOGIST** for routine check-ups related to your transplant?

_____ TIMES PER YEAR

51 53

230. How far do you have to travel **ONE WAY** to see your cardiologist?

NUMBER OF MILES _____

54 57

231. What is the average charge of your cardiologist for this check-up?

$ _____

58 61

232. Approximately what percentage of this do you pay out of your own pocket?

_____ %

233. How frequently do you return to your transplant center for a major follow-up examination (for example, one for which you spend the night)?

_____ TIMES PER YEAR

2 1 7

234. How many days does this examination take?

(Dup 1-6)

_____ DAYS

235. Approximately what percentage of these medical expenses do you pay out of your own pocket?

_____ %

236. How far do you have to travel **ONE WAY** to get to the medical center where you received your heart transplant?

NUMBER OF MILES _____

237. How do you **USUALLY** get to and from the medical center where you had your heart transplant?

(CIRCLE ONE)

AUTOMOBILE (OWNED BY PATIENT) 01

AUTOMOBILE (OWNED BY SOMEONE ELSE) 02

WALKING 03

BICYCLE 04

AIRPLANE/JET 05

CENTER TRANSPORTATION 06

COMMUNITY SERVICE TRANSPORTATION 07

CAB 08

BUS 09

OTHER (SPECIFY) _____ 10

16 17

238. How long does the trip from your home to the transplant center take? *(Include on-route overnight stays.)*

_____ HOURS

18 — 20

239. Has private insurance covered any of your expenses since you were declared a heart transplant candidate?

(CIRCLE ONE)

YES 01

NO ..... 02 **(GO TO Q.245)**

21 22

240. If some of your expenses were covered by **private** insurance, in which period did these covered expenses occur?

(CIRCLE YES OR NO FOR EACH PERIOD)

	YES	NO
A. PRE-TRANSPLANT OR CANDIDACY PERIOD	01	02
B. TRANSPLANT OPERATION PERIOD	01	02
C. POST-TRANSPLANT PERIOD	01	02

241. Have you lost private insurance coverage since becoming a heart transplant candidate?

(CIRCLE ONE)

YES 01

NO ..... 02 **(GO TO Q.243)**

242. What is the reason for your loss of insurance coverage?

PLEASE SPECIFY _____

_____

_____

243. Do you currently have any private insurance coverage?

(CIRCLE ONE)

YES 01

NO 02

244. Have you been trying to obtain (additional) private insurance coverage?

(CIRCLE ONE)

YES 01

NO 02

245. Do you feel you've been denied private insurance coverage because you are a heart transplant recipient?

(CIRCLE ONE)

YES 01

NO 02

37 38

246. Now we would like you to answer a few questions to get a better picture of your current financial situation. Approximately what was your total family income from all sources in 1982? Please include wages, salary, tips, commissions, and net income from own business, professional practice, partnership or farm, dividends, interest, annuities, rents, pension and disability benefits, social security, welfare payments, and gifts.

	APPROXIMATE 1982 INCOME BEFORE TAXES	
A. YOUR WAGES AND/OR SALARY	$ _____	39 _ _ _ _ _ _ 45
B. SPOUSE WAGES AND/OR SALARY	$ _____	46 _ _ _ _ _ _ 52
C. INCOME FROM PENSIONS, SOCIAL SECURITY, DISABILITY BENEFITS	$ _____	53 _ _ _ _ _ _ 59
D. INCOME FROM ALL OTHER SOURCES	$ _____	60 _ _ _ _ _ _ 66
E. TOTAL	$ _____	67 _ _ _ _ _ _ 73

247. Finally, we would like to get a very rough idea of your general financial situation by comparing your assets with any debts that you may have. To do this, first estimate the amount of money that you would have if you were to sell your house, cars and other personal property and then pay-off all mortgages, car loans and other debts. Next, add to this any money that you have in checking and savings accounts, credit unions, stocks, bonds, and mutual funds. Roughly how much do you think that you would have?

(CIRCLE ONE)

LESS THAN $10,000	01
$10,000 - $24,999	02
$25,000 - $49,999	03
$50,000 - $99,999	04
$100,000 - $199,999	05
$200,000 or MORE	06

74 75

2 1 8
78 80

INTRODUCTION TO THE SICKNESS IMPACT PROFILE

To conclude this questionnaire, we would like you to answer a standard set of questions often used to compare groups of people with different health problems. These questions are intended to measure the extent to which sickness has an impact on your ability to do certain activities. Some of the questions may seem quite similar to those you have just answered. However, it is necessary to ask **all** of the questions to maintain the standardized nature of the Sickness Impact Profile.

We realize that this questionnaire has already taken a considerable amount of your time and effort. We would like you to stop at this point and complete the final part of the questionnaire tomorrow which will take about 20 minutes. Instructions for the Sickness Impact Profile are on the following page.

INSTRUCTIONS

PLEASE READ THE FOLLOWING INTRODUCTION **BEFORE** YOU READ THE QUESTIONNAIRE. IT IS VERY IMPORTANT THAT EVERYONE COMPLETING THE QUESTIONNAIRE FOLLOWS THE SAME INSTRUCTIONS.

INTRODUCTION TO RESPONDENT

You have certain activities that you do in carrying on your life. Sometimes you do all of these activities. Other times, because of your state of health, you don't do these activities in the usual way: you may cut some out; you may do some for shorter lengths of time; you may do some in different ways. These changes in your activities might be recent or longstanding. We are interested in learning about **any** changes that describe you today and are related to your state of health.

The questionnaire booklet lists statements that people have told us describe them when they are not completely well. Whether or not you consider yourself sick, there may be some statements that will stand out because they describe **you** today and are related to your state of health. As you read the questionnaire, think of **yourself today**. When you read a statement that you are **sure** describes **you** and is related to your **health,** place a check on the line to the right of the statement. For example:

I am not driving my car ✓

If you have not been driving for some time because of your health, and are still not driving today, you should respond to this statement.

On the other hand, if you never drive or are not driving today because your car is being repaired, the statement, "I am not driving my car" is **not** related to your health and you should **not** check it. If you simply are driving less, or are driving short distances, and feel that the satement only partially describes you, **do not** check it. In all of these cases you would leave the line to the right of the statement blank. For example:

I am not driving my car _____

Remember that we want you to check this statement **only** if you are **sure** it describes you today and is related to your state of health.

Read the introduction to each group of statements and then consider the statements in the order listed. While some of the statements may not apply to you, we ask that you please read **all** of them. Check those that describe you as you go along. Some of the statements will differ only in a few words, so please read each one carefully. While you may go back to change a response, your first answer is usually the best. Please do not read ahead in the booklet.

Once you have started the questionnaire, it is very important that you complete it within one day (24 hours).

If you find it hard to keep your mind on the statements, take a short break and then continue. When you have read all of the statements on a page, put a check in the BOX in the lower right-hand corner. If you have any questions, please refer back to these instructions.

Please do not discuss the statements with anyone, including family members, while doing the questionnaire.

Now turn to the questionnaire booklet and read the statements. Remember we are interested in the recent or longstanding changes in your activities that are related to your health.

(SR-0499)

PLEASE RESPOND TO **ONLY** THOSE STATEMENTS THAT YOU ARE **SURE** DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

(Dup 1-6)

248. I spend much of the day lying down in order to rest _____ (083)

249. I sit during much of the day _____ (049)

250. I am sleeping or dozing most of the time--day and night _____ (104)

251. I lie down more often during the day in order to rest _____ (058)

252. I sit around half-asleep _____ (084)

253. I sleep less at night, for example, wake up too early, don't fall asleep for a long time, awaken frequently _____ (061)

254. I sleep or nap more during the day _____ (060)

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE ☐

(EB-0705)

PLEASE RESPOND TO **ONLY** THOSE STATEMENTS THAT YOU ARE **SURE** DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

255. I say how bad or useless I am, for example, that I am a burden on others _____ (087)

256. I laugh or cry suddenly _____ (068)

257. I often moan and groan in pain or discomfort _____ (069)

258. I have attempted suicide _____ (132)

259. I act nervous or restless _____ (046)

260. I keep rubbing or holding areas of my body that hurt or are uncomfortable _____ (062)

261. I act irritable and impatient with myself, for example, talk badly about myself, swear at myself, blame myself for things that happen _____ (078)

262. I talk about the future in a hopeless way _____ (089)

263. I get sudden frights _____ (074)

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE ☐

2 1 9

CM-2003)

PLEASE RESPOND TO **ONLY** THOSE STATEMENTS THAT YOU ARE **SURE** DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

(Dup 1-6)

264. I make difficult moves with help, for example, getting into or out of cars, bathtubs _____ (084)

265. I do not move into or out of bed or chair by myself but am moved by a person or mechanical aid _____ (121)

266. I stand only for short periods of time _____ (072)

267. I do not maintain balance _____ (098)

268. I move my hands or fingers with some limitation or difficulty _____ (064)

269. I stand up only with someone's help _____ (100)

270. I kneel, stoop, or bend down only by holding on to something _____ (064)

271. I am in a restricted position all the time _____ (125)

272. I am very clumsy in body movements _____ (068)

273. I get in and out of bed or chairs by grasping something for support or using a cane or walker _____ (082)

274. I stay lying down most of the time _____ (113)

275. I change position frequently _____ (030)

276. I hold on to something to move myself around in bed _____ (086)

277. I do not bathe myself completely, for example, require assistance with bathing _____ (089)

278. I do not bathe myself at all, but am bathed by someone else _____ (115)

279. I use bedpan with assistance _____ (114)

280. I have trouble getting shoes, socks, or stockings on _____ (057)

281. I do not have control of my bladder _____ (124)

282. I do not fasten my clothing, for example, require assistance with buttons, zippers, shoelaces _____ (074)

283. I spend most of the time partly undressed or in pajamas _____ (074)

284. I do not have control of my bowels _____ (128)

285. I dress myself, but do so very slowly _____ (043)

286. I get dressed only with someone's help _____ (088)

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE ☐

2 2 0

(HM-0668)

THIS GROUP OF STATEMENTS HAS TO DO WITH ANY WORK YOU USUALLY DO IN CARING FOR YOUR HOME OR YARD, CONSIDERING JUST THOSE THINGS THAT YOU DO. PLEASE RESPOND TO **ONLY** THOSE STATEMENTS THAT YOU ARE **SURE** DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

(Dup 1-6)

287. I do work around the house only for short periods of time or rest often _____ (054) — — — (7–9)

288. I am doing **less** of the regular daily work around the house than I would usually do _____ (044) — — —

289. I am not doing **any** of the regular daily work around the house that I would usually do _____ (086) — — — (13–15)

290. I am not doing **any** of the maintenance or repair work that I would usually do in my home or yard _____ (062) — — —

291. I am not doing **any** of the shopping that I would usually do _____ (071) — — — (19–21)

292. I am not doing **any** of the house cleaning that I would usually do _____ (077) — — —

293. I have difficulty doing handwork, for example, turning faucets, using kitchen gadgets, sewing, carpentry _____ (069) — — — (25–27)

294. I am not doing **any** of the clothes washing that I would usually do _____ (077) — — —

295. I am not doing heavy work around the house _____ (044) — — —

296. I have given up taking care of personal or household business affairs, for example, paying bills, banking, working on budget _____ (064) — — — (34–36)

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE ☐

(M-0719)

PLEASE RESPOND TO **ONLY** THOSE STATEMENTS THAT YOU ARE **SURE** DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

297. I am getting around only within one building _____ (086)

298. I stay within one room _____ (106)

299. I am staying in bed more _____ (081)

300. I am staying in bed most of the time _____ (109)

301. I am not now using public transportation _____ (041)

302. I stay home most of the time _____ (056)

303. I am only going to places with restrooms nearby _____ (056)

304. I am not going into town _____ (048)

305. I stay away from home only for brief periods of time _____ (054)

306. I do not get around in the dark or in unlit places without someone's help _____ (072)

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE ☐

2 2 1

(SI-1450)

PLEASE RESPOND TO **ONLY** THOSE STATEMENTS THAT YOU ARE **SURE** DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

(Dup 1-6)

307. I am going out less to visit people _____ (044) — — — (7–9)

308. I am not going out to visit people at all _____ (101) — — —

309. I show less interest in other people's problems, for example, don't listen when they tell me about their problems, don't offer to help _____ (067) — — — (13–15)

310. I often act irritable toward those around me, for example, snap at people, give sharp answers, criticize easily _____ (084) — — —

311. I show less affection _____ (052) — — — (19–21)

312. I am doing fewer social activities with groups of people _____ (036) — — —

313. I am cutting down the length of visits with friends _____ (043) — — — (25–27)

314. I am avoiding social visits from others _____ (080) — — —

315. My sexual activity is decreased _____ (051) — — — (31–33)

316. I often express concern over what might be happening to my health _____ (052) — — —

317. I talk less with those around me _____ (056) — — — (37–39)

318. I make many demands, for example, insist that people do things for me, tell them how to do things _____ (088) — — —

319. I stay alone much of the time _____ (086) — — — (43–45)

320. I act disagreeable to family members, for example, I act spiteful, I am stubborn _____ (088) — — — (46–48)

321. I have frequent outbursts of anger at family members, for example, strike at them, scream, throw things at them _____ (119)

322. I isolate myself as much as I can from the rest of the family _____ (102)

323. I am paying less attention to the children _____ (064)

324. I refuse contact with family members, for example, turn away from them _____ (115)

325. I am not doing the things I usually do to take care of my children or family _____ (079)

326. I am not joking with family members as I usually do _____ (043)

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE ☐

2 2 2

(A-0842)

PLEASE RESPOND TO **ONLY** THOSE STATEMENTS THAT YOU ARE **SURE** DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

(Dup 1-6)

327.	I walk shorter distances or stop to rest often	(048)	7 9
328.	I do not walk up or down hills	(056)	
329.	I use stairs only with mechanical support, for example, handrail, cane, crutches	(067)	13 15
330.	I walk up or down stairs only with assistance from someone else	(076)	
331.	I get around in a wheelchair	(096)	19 21
332.	I do not walk at all	(105)	
333.	I walk by myself but with some difficulty, for example, limp, wobble, stumble, have stiff leg	(055)	25 27
334.	I walk only with help from someone	(088)	
335.	I go up and down stairs more slowly, for example, one step at a time, stop often	(054)	31 33
336.	I do not use stairs at all	(083)	
337.	I get around only by using a walker, crutches, cane, walls, or furniture	(079)	
338.	I walk more slowly	(035)	40 42

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE ☐

(AB-0777)

PLEASE RESPOND TO **ONLY** THOSE STATEMENTS THAT YOU ARE **SURE** DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

339. I am confused and start several actions at a time _____ (090)

340. I have more minor accidents, for example, drop things, trip and fall, bump into things _____ (075)

341. I react slowly to things that are said or done _____ (059)

342. I do not finish things I start _____ (067)

343. I have difficulty reasoning and solving problems, for example, making plans, making decisions, learning new things _____ (084)

344. I sometimes behave as if I were confused or disoriented in place or time, for example, where I am, who is around, directions, what day it is _____ (113)

345. I forget a lot, for example, things that happened recently, where I put things, appointments _____ (078)

346. I do not keep my attention on any activity for long _____ (067)

347. I make more mistakes than usual _____ (064)

348. I have difficulty doing activities involving concentration and thinking _____ (080)

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE ☐

2 2 3

(C-0725)

PLEASE RESPOND TO **ONLY** THOSE STATEMENTS THAT YOU ARE **SURE** DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

(Dup 1-6)

---

349. I am having trouble writing or typing _____ (070)

350. I communicate mostly by gestures, for example, moving head, pointing, sign language _____ (102)

351. My speech is understood only by a few people who know me well _____ (093)

352. I often lose control of my voice when I talk, for example, my voice gets louder or softer, trembles, changes unexpectedly _____ (083)

353. I don't write except to sign my name _____ (063)

354. I carry on a conversation only when very close to the other person or looking at him _____ (067)

355. I have difficulty speaking, for example, get stuck, stutter, stammer, slur my words _____ (076)

356. I am understood with difficulty _____ (087)

357. I do not speak clearly when I am under stress _____ (064)

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE ☐

THE NEXT GROUP OF STATEMENTS HAS TO DO WITH ANY WORK YOU USUALLY DO OTHER THAN MANAGING YOUR HOME. BY THIS WE MEAN ANYTHING THAT YOU REGARD AS WORK THAT YOU DO ON A REGULAR BASIS.

DO YOU USUALLY DO WORK OTHER THAN MANAGING YOUR HOME? YES NO

34 35

➔ IF YOU ANSWERED YES, GO ON TO THE NEXT PAGE

➔ IF YOU ANSWERED NO:

ARE YOU RETIRED? YES NO

36 37

IF YOU ARE RETIRED, WAS YOUR RETIREMENT RELATED TO YOUR HEALTH? YES NO

38 39

IF YOU ARE NOT RETIRED, BUT ARE **NOT** WORKING, IS THIS RELATED TO YOUR HEALTH? YES NO

40 41

➔ NOW SKIP THE NEXT PAGE

(W-0515)

IF YOU ARE NOT WORKING AND IT IS **NOT** BECAUSE OF YOUR HEALTH, PLEASE SKIP THIS PAGE

NOW CONSIDER THE WORK YOU DO AND RESPOND TO **ONLY** THOSE STATEMENTS THAT YOU ARE **SURE** DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH. *(IF TODAY IS A SATURDAY OR SUNDAY OR SOME OTHER DAY THAT YOU WOULD USUALLY HAVE OFF, PLEASE RESPOND AS IF TODAY WERE A WORKING DAY.)*

358. I am not working at all _____ (361)

(IF YOU CHECK THIS STATEMENT, SKIP TO THE NEXT PAGE)

359. I am doing part of my job at home _____ (037)

360. I am not accomplishing as much as usual at work _____ (055)

361. I often act irritable toward my work associates, for example, snap at them, give sharp answers, criticize easily _____ (080)

362. I am working shorter hours _____ (043)

363. I am doing only light work _____ (050)

364. I work only for short periods of time or take frequent rests _____ (061)

365. I am working at my usual job but with some changes, for example, using different tools or special aids, trading some tasks with other workers _____ (034)

366. I do not do my job as carefully and accurately as usual _____ (062)

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE ☐

42 44 48 50 54 56 60 62 66 68 78 80

2 2 4

(RP-0422)

THIS GROUP OF STATEMENTS HAS TO DO WITH ACTIVITIES YOU USUALLY DO IN YOUR FREE TIME. THESE ACTIVITIES ARE THINGS THAT YOU MIGHT DO FOR RELAXATION, TO PASS THE TIME, OR FOR ENTERTAINMENT. PLEASE RESPOND TO **ONLY** THOSE STATEMENTS THAT YOU ARE **SURE** DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

(Dup 1-6)

367. I do my hobbies and recreation for shorter periods of time _____ (039) — — — 9

368. I am going out for entertainment less often _____ (036) — — —

369. I am cutting down on **some** of my usual inactive recreation and pastimes, for example, watching TV, playing cards, reading _____ (059) — — — 13 15

370. I am not doing **any** of my usual inactive recreation and pastimes, for example, watching TV, playing cards, reading _____ (084) — — —

371. I am doing more inactive pastimes in place of my other usual activities _____ (051) — — — 19 21

372. I am doing fewer community activities _____ (033) — — —

373. I am cutting down on **some** of my usual physical recreation or activities _____ (043) — — —

374. I am not doing **any** of my usual physical recreation or activities _____ (077) — — — 28 30

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE ☐

(E-0705)

PLEASE RESPOND TO **ONLY** THOSE STATEMENTS THAT YOU ARE **SURE** DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

375. I am eating much less than usual _____ (037)

376. I feed myself but only by using specially prepared food or utensils _____ (077)

377. I am eating special or different food, for example, soft food, bland diet, low-salt, low-fat, low-sugar _____ (043)

378. I eat no food at all but am taking fluids _____ (104)

379. I just pick or nibble at my food _____ (059)

380. I am drinking less fluids _____ (036)

381. I feed myself with help from someone else _____ (099)

382. I do not feed myself at all, but must be fed _____ (117)

383. I am eating no food at all, nutrition is taken through tubes or intravenous fluids _____ (133)

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE ☐

2 2 5

CONCLUSION OF THE QUESTIONNAIRE

We at the Battelle Human Affairs Research Centers very much appreciate the time and effort you have put into this questionnaire. The information you have provided is essential to meeting the objectives of the National Heart Transplantation Study. If you have any comments about this questionnaire, please record them on the following page. Also, if you would like to have a brief summary of the results of the study, which will be available by the end of the year, please fill out the enclosed form which will be filed separately from the questionnaire.

INSTRUCTIONS FOR RETURNING STUDY MATERIALS:

In order to keep your name separate from the questionnaire, we have provided two pre-addressed envelopes. You do **not** have to place postage on these envelopes.

- THE LARGER MANILA ENVELOPE SHOULD CONTAIN **ONLY** THE QUESTIONNAIRE.
- THE SMALLER MANILA ENVELOPE SHOULD CONTAIN THE FOLLOWING:
  - White copy of the General Consent Form
  - Yellow copy of the General Consent Form
  - White copy of the Authorization For Review of Medical Records and Hospital Billing Information
  - Yellow copy of the Authorization For Review of Medical Records and Hospital Billing Information
  - Request for a summary of the study (optional).

Remember to keep the pink copies of the General Consent Form and the Authorization for Review of Medical Records and Hospital Billing Information for your own records.

In closing, if you should have any questions whatsoever, please do not hesitate to make a collect call to Dr. Roger W. Evans' office at (206) 525-3130, extension 457. Once again, we are very grateful for your participation in this very important study.

COMMENTS

Yes, I would like to receive a summary of the National Heart Transplantation Study.

Name _____

Address _____

City _____ State _____ Zip Code _____

APPENDIX 5-B

PATIENT ROSTER FORMS

TRANSPLANT CENTER NAME: _____

HEART TRANSPLANT PATIENT ROSTER

This list should contain the names of all patients transplanted at your center since your transplant program began through June 30, 1983. Patients should be in chronological order according to the date of their most recent transplant. Use as many pages as necessary to list all your patients.

PATIENT NAME (LAST, FIRST)	MONTH AND YEAR OF LAST TRANSPLANT (MO. YEAR)	CURRENT PATIENT AGE (YEARS)	WAS THE PATIENT DISCHARGED FROM THE HOSPITAL ALIVE? (Y/N)	HOW MANY TRANSPLANTS HAS THE PATIENT HAD? (1, 2, 3)	IS THE PATIENT CURRENTLY LIVING OR DECEASED? (L/D)	IF PATIENT IS DECEASED, RECORD DATE OF DEATH (MO. YEAR)

APPENDIX 5-C

GENERAL INFORMATION FORM
LIVING HEART TRANSPLANT RECIPIENTS
AND THEIR FAMILY OR HOUSEHOLD MEMBER RESPONDENTS

TRANSPLANT CENTER NAME: _____

TODAY'S DATE: _____

GENERAL INFORMATION FORM FOR LIVING HEART TRANSPLANT RECIPIENTS
AND THEIR FAMILY OR HOUSEHOLD MEMBER RESPONDENTS

1. What is this patient's name?

_____
FIRST LAST

2. What is this patient's six digit study identification number?

___/___/___/___/___

3. Has this patient been asked to participate in the National Heart Transplantation Study?

(CIRCLE ONE)

YES..... 01

NO 02

4. Has this patient agreed to participate in the study?

(CIRCLE ONE)

YES, THE PATIENT WANTS TO PARTICIPATE ..... 01 CONTINUE

NO, THE PATIENT DOES NOT WANT TO PARTICIPATE..... 02 STOP

5. What is this patient's current mailing address?

STREET _____

APT. NO. _____

CITY, STATE _____, _____

ZIP CODE _____

6. What is this patient's current telephone number?

(_____)_____
AREA CODE NUMBER

☐ CHECK THIS BOX IF THE PATIENT HAS NO PHONE

7. If the patient does not have a telephone, is there a telephone number at which he/she may receive messages?

(_____)_____
AREA CODE NUMBER

8. Has a family or household member been identified who has agreed to participate in this study?

(CIRCLE ONE)

YES 01

NO ..... 02 (KEEP TRYING)

9. What is the name of a family or household member to whom a questionnaire can be mailed?

_____
FIRST LAST

10. What is this person's relationship to the patient (e.g., spouse, brother, sister, mother, father, aunt, uncle, etc.)?

_____
SPECIFY

11. If different from the patient's, what is this person's current mailing address?

STREET _____

APT. NO. _____

CITY, STATE _____,_____

ZIP CODE _____

12. If different from the patient's, what is this person's current telephone number?

(_____)_____
AREA CODE NUMBER

☐ CHECK THIS BOX IF THE PERSON HAS NO PHONE

13. If the person does not have a telephone, is there a phone number at which he/she may receive messages?

(_____)_____
AREA CODE NUMBER

APPENDIX 5-D

RECIPIENT CONTACT FORM

NATIONAL HEART TRANSPLANTATION STUDY
RECIPIENT

NAME:_____ I.D.#_____

CITY/STATE:_____

PHONE: (___)_____

TRANSPLANT CENTER:_____

STAFF MEMBER CONTACT: _____

DATE RESPONDENT CONTACTED: _____

	DATE	INITIALS
SURVEY PACKET MAILED		
INITIAL FOLLOW-UP CALL		
SURVEY MATERIALS RETURNED		

ADDITIONAL COMMUNICATION

TO

FROM

APPENDIX 5-E

GENERAL CONSENT FORM

NATIONAL HEART TRANSPLANTATION STUDY

GENERAL CONSENT FORM

You are being asked to participate in the first major study of heart transplant recipients and their family or household members. This study, conducted by the Battelle Human Affairs Research Centers in Seattle, Washington, is concerned not only with the financial aspects, but with all aspects of heart transplantation including how well recipients and their families are doing at this time. We are also interested in any problems you may have had or are currently having. For clarity, we have divided the study into several major research components. These components include: (1) an estimate of the number of people requiring heart transplants in the United States; (2) the demonstrated value of heart transplantation as a medical procedure; (3) the availability of donor hearts; (4) the cost of performing a heart transplant and the routine medical management that occurs thereafter; (5) the quality of life enjoyed by heart transplant recipients both before and after their heart transplant; and (6) various legal and ethical dilemmas that surround heart transplantation as a procedure not suitable for everyone.

Six heart transplant centers have been selected by the Federal government to participate in the study. They are: (1) University of Arizona (Tucson, AZ); (2) Columbia Presbyterian Hospital and Medical Center (New York, NY); (3) Medical College of Virginia (Richmond, VA); (4) University of Minnesota (Minneapolis, MN); (5) University of Pittsburgh (Pittsburgh, PA); and (6) Stanford University Medical Center (Stanford, CA). As participants in the study, each transplant center agreed to contact their heart transplant recipients and the recipients' families for purposes of cooperating with us in the study. Your transplant center informed us that you were interested in the study.

If you agree to participate in the National Heart Transplantation Study recipient survey, you are asked to fill out the questionnaire which has been sent to you with this consent form. The study is designed to give us information about your health, your family and social life, your financial situation, your overall quality of life, and your experience with rehabilitation and social service agencies.

Your participation in this study is purely voluntary. You may refuse to fill out the questionnaire altogether, or, if you decide to participate, you may leave any question or item unanswered.

While we would also like to obtain some information contained in the medical and billing records kept by your transplant center, your signature on this consent form gives us permission *only* to use the information you supply by your answers to the questionnaire; it does *not* give us permission to see your medical records or hospital billing information. We will review those items only if you give us permission to do so by signing the "Authorization for Review of Medical Records and Hospital Billing Information" form. If you give us permission to see your medical records, only information about your heart transplant and treatment will be studied. In addition, you may restrict our access further by indicating on the authorization form that you wish us to examine the record of your treatment only between certain dates, or that you do not wish to disclose to us information in your medical records about any condition or subject matter.

All information that we receive based on your answers to the questionnaire, your medical records, and hospital billing records is kept *strictly confidential.* We will give no one, including the government or your doctors, the information you provide to us that would personally identify you. Your name will not appear on the questionnaire. Once the information has been collected, it will no longer be associated with your name.

There is very little risk in participating in the study, except perhaps possible fatigue or discomfort during completion of the survey. If you decide not to participate in this study, or if you choose not to answer all of the questions, your treatment or any benefits you now receive as a heart transplant recipient will not be affected in any way.

If you have any questions about how we intend to use the information you provide, or about the meaning of any item of the questionnaire, you may make a collect call to the National Heart Transplantation Study project director, Dr. Roger W. Evans, at (206) 525-3130. We hope that you will agree to participate in this important study; the results of this survey will provide a better understanding of the current status of people who have received heart transplants.

With the above assurances that my rights will be protected, I now give my consent to participate in this study.

Name: _____
(Please Print)

_____
(Signature)

Date: _____

OMB 0938-0189
(Exp. 12.83)

APPENDIX 5-F

CONSENT FORM AUTHORIZING THE REVIEW OF MEDICAL RECORDS AND HOSPITAL BILLING INFORMATION

NATIONAL HEART TRANSPLANTATION STUDY

AUTHORIZATION FOR REVIEW OF MEDICAL RECORDS AND HOSPITAL BILLING INFORMATION

Name: _____
(Please Print)

Place Transplant Performed: _____

Date Transplant Performed: _____

This form authorizes a data abstractor for the National Heart Transplantation Study being conducted by the Battelle Human Affairs Research Centers in Seattle, Washington, to study the hospital billing records and all or part of the medical records that apply to the treatment of my heart disease, my heart transplant, and any associated care as I have indicated below. (Please mark the appropriate responses.)

Authorization to Review Medical Records

_____ I give my permission to review and, if necessary, to make a copy of the *complete record* of the history of my heart disease and treatment.

_____ I wish to restrict access to my medical records as indicated below:

_____

_____

_____

Authorization to Review Hospital Billing Records

_____ I give my permission to review and, if necessary, make a copy of the hospital billing records pertaining to my treatment for heart disease, my transplant, and any associated care.

Signature: _____ Date _____

This authorization must be signed by the recipient and will be valid for one year from date, unless otherwise directed by the recipient.

OMB 0938-0189
(Exp. 12-83)

APPENDIX 5-G

REQUEST FORM FOR SUMMARY OF STUDY RESULTS

Yes, I would like to receive a summary of the National Heart Transplantation Study.

Name _____

Address _____

City _____ State _____ Zip Code _____

APPENDIX 5-H

COVER LETTER

Battelle
Human Affairs Research Centers
4000 N.E. 41st Street
P.O. Box C-5395
Seattle, Washington 98105
Telephone (206) 525-3130
Cable BATSEA

December --, 1983

[Name and address of living heart transplant recipient]

Dear :

As you probably know, we at the Battelle Human Affairs Research Centers are currently conducting a nationwide study of heart transplantation. As part of this study, [name of transplant center inserted here] and five other heart transplant programs in the United States are helping us to collect important information on heart transplant recipients and their families. We understand that you have been contacted by someone from [name of transplant center inserted here] and that you have indicated a willingness to participate in the study.

Enclosed is a copy of the Heart Transplant Recipient Questionnaire which we would like you to complete. Please read the introduction to the questionnaire before you begin. The questionnaire is long and detailed. However, we do not expect you to complete it in a single sitting. In fact, to answer some of the questions you may wish to consult your records.

Within the next week or so, a survey assistant from Battelle will be calling you to answer any questions that you may have regarding the survey. If possible, it would be helpful if you would complete as much of the questionnaire as you can before you receive the call.

Thank you very much for your help in this important study.

With my kindest regards,

Roger W. Evans, Ph.D.
Project Director
National Heart Transplantation Study

RWE:mg
Enclosures

CHAPTER 6

THE ABSTRACTION OF MEDICAL AND HOSPITAL RECORDS

Lair Showalter, B.A.
Roger W. Evans, Ph.D.
Diane L. Manninen, Ph.D.
Health and Population Study Center
Battelle Human Affairs Research Centers
4000 N.E. 41st Street
Seattle, Washington 98105

A. INTRODUCTION

The abstraction of data from medical and hospital records of both potential and actual heart transplant recipients were two of several primary data collection efforts undertaken as part of the National Heart Transplantation Study. Although not all are described in this chapter, five separate data collection efforts were conducted. They include:

- a survey of living heart transplant recipients
- a survey of family or household members of living heart transplant recipients
- a survey of family or household members of deceased heart transplant recipients
- data abstraction of medical and hospital records of recipients
- data abstraction of medical and hospital records of nonrecipients

This chapter describes the procedures used in abstracting relevant data from the medical and hospital records maintained by each of the participating transplant centers. The survey of living heart transplant recipients is described in detail in Chapter 5, while the surveys of family and household members of both living and deceased transplant recipients are provided in Chapter 7 of this report.

To meet the primary objectives of the study, data on all aspects of heart transplantation were required. Of primary importance were data on the social and economic costs and benefits of the procedure. Although living heart transplant recipients were an excellent primary source for certain types of data (such as quality of life), there was a considerable amount of medical and cost data which the recipient was

unlikely to be able to provide. In other instances where the recipient has died, the most appropriate source of data was the patient's medical and hospital records. Furthermore, since not all patients referred for a heart transplant become heart transplant recipients, the only records available to provide a profile on those who were not transplanted were the records maintained by the heart transplant center.

In order to systematically assemble the data required to meet the objectives of the study, two Medical and Hospital Records Data Abstraction Forms were developed and used to record relevant medical history and treatment data, as well as financial data, from the medical and hospital records maintained by the six participating heart transplant centers (University of Arizona Health Sciences Center, Columbia Presbyterian Medical Center, Medical College of Virginia, University of Minnesota, University of Pittsburgh, and Stanford University Medical Center). The first data abstraction form was designed for patients who had been accepted as heart transplant candidates and had received a heart transplant. This included both living and deceased heart transplant recipients. The second data abstraction form was designed for patients who had been evaluated as potential heart transplant recipients but for one of various reasons had not received a heart transplant. Thus, the two data abstraction forms were developed as a mechanism by which uniform data could be collected on potential and actual heart transplant recipients.

The Medical and Hospital Data Abstraction Forms, although largely concerned with the medical aspects of transplantation, also included substantial amounts of data that were critical to other components of

the study. For example, dates were established for conducting the survival analyses, patient level of functioning (both physical and cardiac) was assessed, and data appropriate to the assessment of the cost of heart transplantation were compiled. Thus, the Medical and Hospital Records Data Abstraction Forms were truly multipurpose instruments.

B. THE MEDICAL AND HOSPITAL RECORDS DATA ABSTRACTION FORMS

An understanding of the process by which patients are referred to heart transplant programs is essential to understanding the structure of the two Medical and Hospital Records Data Abstraction Forms. Patients can be referred to a transplant program in one of several ways and their evaluations may vary in extent. In some instances a referring cardiologist will call the transplant program and describe the details of a patient's case. Based on this information, the transplant program may turn the patient down as a possible candidate or may request that additional information be sent for further consideration. Most transplant programs do not keep records on simple telephone inquiries. If, however, the results of tests and evaluations are sent, the program will usually start a file.

After receiving materials from the referring cardiologist, the program then decides whether or not the patient should come in for a complete evaluation. If it is decided that the patient should not have a complete evaluation, the patient is refused as a possible transplant candidate. If a complete evaluation is performed, then a decision is made to accept or reject the patient as an official transplant candidate based on the results of several tests and studies.

Those patients who are accepted as candidates must then wait for the identification of a suitable heart donor. In a few cases during this period the candidate's heart status and health improve to the extent that he/she is deselected. Another possibility is that the candidate may die before a suitable donor is identified. To take into account the several stages of the evaluation and transplantation processes, two separate forms were developed with which to compile data for all the possible patient groups.

1. SAMPLE DESIGN

Data were collected on all heart transplant recipients (both living and deceased), as well as all patients who had been referred to the six participating heart transplant centers between January 1, 1978 and June 30, 1983. Data were collected on transplant patients under 18 years of age and those currently residing outside the United States, although these patients were not included in the heart transplant recipients survey. The only transplant patients for whom medical and hospital records data were not obtained were those patients who refused to provide written consent for the collection of these data. Thus, the Transplant Recipient Medical and Hospital Records Data Abstraction Form was completed for two patient groups:

- patients accepted as heart transplant candidates who received a heart transplant and are living
- patients accepted as heart transplant candidates who received a heart transplant and are deceased

Since there are other heart transplant programs in the U.S., the patients at the six centers that participated in the study did not

constitute the universe of all heart transplant recipients. However, in 1983 these six programs performed 80.2% of all heart transplants that were performed in the United States.

The Nonrecipient Medical and Hospital Records Data Abstraction Form was completed for all patients who were evaluated by one of the six participating transplant centers between January 1, 1978 and June 30, 1983, but who did not receive a heart transplant for one of several reasons. This includes the following patient groups:

- patients turned down as suitable candidates for a heart transplant
- patients who were accepted as heart transplant candidates but died before receiving one
- patients who were selected as heart transplant candidates but were later deselected or are still awaiting the identification of a suitable donor
- patients who were accepted as heart transplant candidates but were not transplanted by the patient's choice
- patients who were referred or evaluated for transplantation but no decision and no further contact was made
- patients who were referred or evaluated for transplantation but died before a decision was made
- patients who were referred or evaluated for transplantation but were referred to or transplanted at another transplant program

Since some transplant programs (most notably the Stanford University Medical Center) began performing heart transplants prior to 1978, these patients are a subset of all patients referred to the

participating heart transplant programs since the initiation of heart transplantation in the United States.

2. CONTENT OF THE DATA ABSTRACTION FORMS

The two Medical and Hospital Records Data Abstraction Forms vary in length and content. The Transplant Recipient form is longer and allows for more extensive data collection about patients who received a heart transplant, whether he/she is currently living or deceased. The types of data obtained in the Transplant Recipient form include:

- patient referral data
- demographic and patient selection data
- functional status data
- financial and insurance data
- evaluation period financial data
- candidacy period financial data
- mortality data
- histocompatibility data
- donor heart procurement data
- immunosuppression protocol data
- hospitalization history data
- infection history data
- rejection history data
- organ procurement financial data
- transplantation period financial data

A copy of the Transplant Recipient Medical and Hospital Records Data Abstraction Form is included as Appendix 6-A

The Nonrecipient Medical and Hospital Records Data Abstraction Form is a multi-part form, of which separate parts were targeted toward particular patient groups. Minimal data were obtained on those patients whose records were sent to the heart transplant center for consideration. Additional detailed information was required for patients who underwent a thorough evaluation.

The types of data obtained in the Nonrecipient Medical and Hospital Records Data Abstraction Form include:

- referral data
- demographic and patient selection data
- functional status data
- financial and insurance data
- evaluation period financial data
- reasons why patients were turned down as transplant candidates
- mortality data
- candidacy period financial data
- current status of patients awaiting a heart transplant
- deselection data

A copy of the Nonrecipient Medical and Hospital Records Data Abstraction Form is included as Appendix 6-B.

3. DATA COLLECTION PROTOCOL

Each of the six participating transplant centers was responsible for hiring staff and completing the Medical and Hospital Records Data Abstracton Forms under subcontract to the Battelle Human Affairs Research Centers. The protocol for data collection at each

heart transplant program was established individually by center. Given varying hospital recordkeeping systems, it was impossible to specify a uniform protocol to be followed at all sites. Furthermore, completing the forms often required consultation of records at numerous locations within the hospital, including the Department of Cardiovascular or Cardiothoracic Surgery, the financial records or billing office, and the medical records department. Thus, at each center an individual or team of assistants worked to gather the data and complete the forms.

The six transplant centers provided Battelle with complete rosters containing names of all living and deceased heart transplant recipients. A copy of the form on which patient rosters were recorded is attached as Appendix 6-C. A study identification number was assigned to each recipient. This same number was also used to identify the recipient in the Heart Transplant Recipient Survey and the Family or Household Member Surveys. The recipient's assigned identification number was stamped in three places on the Transplant Recipient Medical and Hospital Records Data Abstraction Form: (1) the cover, (2) the tear sheet, and (3) on page one in the space provided for patient identification study number. The patient's name was then written on the tear sheet (a perforated page at the beginning of the questionnaire) to provide clear identification of each patient and his/her number to the transplant center.

The data collection forms were then sent to the respective transplant programs. The transplant center staff members were instructed to complete the forms, and remove the tear sheet to retain

for their records, before returning the forms to Battelle. This procedure insured both proper identification and confidentiality.

Similar procedures were followed in completing the Nonrecipient Medical and Hospital Records Data Abstraction Forms. Each transplant center provided Battelle with an estimate of the number of patients for whom forms would be completed. The Nonrecipient Medical and Hospital Records Data Abstraction Forms were stamped with unique study identification numbers and sent to their respective centers. These forms also contained tear sheets that the transplant programs filled out and used to identify patients during data collection. Once the forms were completed, the tear sheets were removed and the forms were returned to Battelle. The names of these patients were never given to Battelle.

Four Battelle survey specialists were assigned to the six transplant centers. The assigments were as follows:

. Arizona Health Sciences Center	Judith Raab
. Columbia Presbyterian Medical Center	Judith Raab
. Medical College of Virginia	Lair Showalter
. University of Minnesota	Cynthia Livak
. University of Pittsburgh	Lisa Bowen
. Stanford University Medical Center	Lisa Bowen, Cynthia Livak, Judith Raab, Lair Showalter

In addition to coding and editing the medical and hospital records data abstraction forms, these survey specialists were responsible for

administering and coding the heart transplant recipient and the family or household member surveys.

After the Medical and Hospital Records Data Abstraction Forms were completed by each center, they were returned to Battelle. The completed data abstraction forms were coded and edited manually by the assigned survey specialist soon after they were received. Because the survey instrument consisted mostly of closed-ended items that were precoded, coding efforts and potential transcription errors were minimized. Quality control was maintained through weekly meetings to discuss questions, resolve problems, and amend the coding key as necessary. When the majority of forms had been received and coded, survey specialists verified each others' work and resolved discrepancies in coding. The verified instruments were then keypunched and 100% verified. Finally, a computer data file was created and the data were cleaned for analysis.

4. CONSENT AND CONFIDENTIALITY PROCEDURES

The following rules applied in obtaining consent for the abstraction of transplant recipient medical and hospital records data:

- For living transplant recipients, consent was obtained for review of their records at the time they completed the "Heart Transplant Recipient Questionnaire."
- For deceased heart transplant recipients whose next-of-kin participated in the study by completing the "Family or Household Member Questionnaire," a separate consent form was signed on behalf of the patient.

In conjunction with the Heart Transplant Recipient Survey (see Chapter 5) and the Family or Household Member Survey (see Chapter 7),

living heart transplant recipients and relatives of deceased heart transplant recipients were asked to sign two consent forms. The purpose of the first form was to acknowledge their willingness to participate in the study, while the second form gave permission for the extraction of information from hospital and medical records. Copies of the two medical and hospital records consent forms--Authorization For Review of Medical Records and Hospital Billing Information--are attached as Appendices 6-D and 6-E.

Respondents were fully informed of the nature and purposes of the study and the uses which were to be made of the data. The consent forms provided Battelle with a written acknowledgement from each individual indicating that they have been informed of:

- the objectives of the study
- the procedures to be followed
- measures to be taken to ensure the information they provide is kept confidential
- possible discomforts or risks associated with their participation
- the purely voluntary nature of their participation and their freedom to refuse any part or discontinue participation in the study at any time.

In a cover letter, respondents were requested to carefully read, and if willing to participate, sign the consent forms and return them to Battelle separately from the survey instrument.

On the consent form, patients and next-of-kin were given the option of denying access to medical records only, to hospital billing records only or to both. Respondents were also able to restrict

access to a certain time period. If a patient refused to sign a consent form providing access to their medical and hospital records, their records were not reviewed. Likewise, if a family member denied access to a deceased patient's records, the records were not reviewed. As seen in Table 6-1, only three patients denied access to their complete records, two denied access to medical information only, and five denied access to hospital billing records.

All medical and hospital records data have remained confidential and respondents anonymous throughout the data collection process. Although the consent forms were signed by the respondent, the forms did not contain the participant's identification number. The Medical and Hospital Records Data Abstraction Forms were stamped with the individual's study identification numbers. Patient's names, however, appeared only on the tear sheets, which were removed by transplant center staff before returning the forms to Battelle.

Completed data abstraction forms were filed separately from the signed consent forms. Lists of transplant recipients and their corresponding identification numbers were kept separately from all data collection instruments. Names of nonrecipients were never given to Battelle. All records were maintained in secure storage areas that were accessible only to authorized personnel. The resulting data files identified patients only by identification number. This procedure has protected the anonymity of the medical and hospital records data and all other information obtained concerning the patient.

Table 6-1
Transplant Recipient Medical and Hospital Records
Data Abstraction Consent Forms

Center	Total Number Recipients	Refused Consent			Total Number Medical Records Forms
		Complete Form	Medical Information	Billing Information	
Arizona	40	1	0	0	39
Columbia	29	0	0	1	29
MCV	37	0	1	0	37
Minnesota	20	0	0	0	20
Pittsburgh	49	0	0	0	49
Stanford	269	2	1	4	267
TOTAL	444	3	2	5	441

C. NUMBER OF COMPLETED DATA ABSTRACTION FORMS

As can be seen in Table 6-2, Medical and Hospital Records Data Abstraction Forms were completed for a total of 441 heart transplant recipients and 842 patients who were evaluated but did not receive a heart transplant at the six participating transplant programs. As was discussed earlier, very few patients denied access to their medical and hospital records. Among 444 transplant recipients, for example, only three patients denied access to their complete records, two denied access to medical information only, and five denied access to hospital billing records (see Table 6-1).

D. CONCLUSION

The abstraction of data from the medical and hospital records of potential and actual heart transplant recipients at the six participating transplant programs has been a costly and time-consuming effort. However, through the success of this data collection effort, a comprehensive data set has been assembled for 441 heart transplant recipients and 842 patients who were evaluated as potential transplant candidates, but for one of several reasons did not receive a transplant. The data set is unique in that it contains medical and cost data not only for heart transplant recipients, but also for those patients who were evaluated but did not receive a transplant. For transplant recipients, medical and cost data were obtained for the evaluation period, as well as for the candidacy and transplantation periods. Other important medical information (such as episodes of infection and rejection) during the post-operative period was also

Table 6-2
Number of Completed Medical and Hospital Records
Data Abstraction Forms

CENTER	RECIPIENT	NONRECIPIENT
Arizona	39	58
Columbia	29	53
MCV	37	138
Minnesota	20	0
Pittsburgh	49	46
Stanford	267	547
TOTAL	441	842

obtained. This data set is extremely valuable in addressing many of the issues involving heart transplantation, including an analysis of patient survival.

APPENDIX 6-A

TRANSPLANT RECIPIENT
MEDICAL AND HOSPITAL RECORDS DATA ABSTRACTION FORM

TRANSPLANT RECIPIENT

MEDICAL AND HOSPITAL RECORDS DATA ABSTRACTION FORM

NATIONAL HEART TRANSPLANTATION STUDY*

Health and Population Study Center
Battelle Human Affairs Research Centers
4000 N.E. 41st Street
Seattle, Washington 98105
Telephone (206) 525-3130

*A project sponsored by the Office of Research and Demonstrations of the Health Care Financing Administration. Contract Number 500-81-0051. Questions concerning this study should be directed to Dr. Roger W. Evans at the Battelle Human Affairs Research Centers.

OMB 0938-0189
(2-83)

NOTE: THIS IS A TEARSHEET

THIS PAGE IS TO BE REMOVED BEFORE THIS FORM IS RETURNED TO THE BATTELLE HUMAN AFFAIRS RESEARCH CENTERS

What is this patient's name, complete address, and telephone number?

Name _____
First Middle Last

Street Address _____
City State Zip Code

Telephone (_____) _____
Area Code

What is this patient's hospital identification number; that is, the number assigned to the patient during the time he/she was being evaluated as a heart transplant candidate?

_____
HOSPITAL IDENTIFICATION NUMBER

CHECK THE BOX PROVIDED BELOW IF THE PATIENT WAS NOT ASSIGNED A NUMBER.

☐ *THIS PATIENT WAS NOT ASSIGNED A HOSPITAL I.D. NUMBER*

INTRODUCTION

This data form should be completed for **ALL** patients who were accepted as a transplant candidate and received a heart transplant at your program regardless of whether he/she is currently living or deceased. Please note that a different data form should be completed for all patients who have been referred to your program for a heart transplant between January 1, 1978 and June 30, 1983 (including patients who have been identified as potential heart transplant recipients and who are still awaiting the identification of a suitable donor). Only patients for whom a telephone inquiry was made, without followup, should be excluded from the study.

PATIENTS FOR WHOM NO FORM SHOULD BE COMPLETED:

- any patient for whom a simple telephone inquiry was made by a referring cardiologist, but no laboratory test data, study results, or psychosocial evaluations were submitted for consideration.

PATIENTS FOR WHOM THIS FORM SHOULD BE COMPLETED:

- any patient accepted as a heart transplant candidate and received a heart transplant regardless of whether he/she is currently living or deceased.

CODES FOR MISSING OR UNAVAILABLE DATA

In any research study, such as the National Heart Transplantation Study, there will always be data which are "missing." The important point, however, is that there are several types of missing data. To make certain that this form is filled out properly and at the same time to provide a clear indication of why certain questions are unanswered, we have adopted a special set of missing data codes as well as specifying conventions for indicating why the data are missing. In completing this form, the following abbreviations should be used to signify missing data:

ABBREVIATION	DEFINITION
DK	**DON'T KNOW** - no data are available to answer the questions as stated in the data collection instrument.
MISSING	**MISSING** - data that were likely to have been available at some point in time, but a review of hospital and medical records does not provide the required data, should be recorded as "missing."
NP	**NOT PERFORMED** - if a given test was not performed and, thus, the test results are unavailable, an "NP" should be recorded on the form.

DEFINITIONS

To assist with the completion of this form, the following definitions are provided:

PRE-EVALUATION PERIOD - For patients who have their evaluation secondary to a hospitalization not initially intended for heart transplant evaluation, the pre-evaluation period is the time period between the date of their initial hospitalization (i.e., admission date) and the date on which additional transplant-related evaluation tests were done. Patients who are hospitalized specifically for purposes of evaluation will not have a pre-evaluation period; however, patients who were already hospitalized before their evaluation will have a pre-evaluation period.

EVALUATION PERIOD - The evaluation period is the period between the date on which heart transplant evaluation tests were performed on the patient and the date the patient was accepted or rejected as a heart transplant candidate.

CANDIDACY PERIOD - The candidacy period is the period between the date the patient was accepted as a heart transplant candidate and the date of the day before the patient received his/her heart transplant. If the patient died prior to receiving a heart transplant, the candidacy period is the period between the date the patient was accepted as a heart transplant candidate and the date of their death.

TRANSPLANTATION PERIOD - The transplantation period is the period between the date the patient received his/her transplant and the date of his/her initial discharge from the hospital following transplant surgery, or the date the patient expired if this occurred prior to initial discharge.

POST-TRANSPLANT PERIOD - The post-transplant period is the period between the date of the patient's initial discharge from the hospital and June 30, 1983 or the date that he/she died.

THESE QUESTIONS ARE FOR THOSE PATIENTS WHO HAVE ACTUALLY RECEIVED A HEART TRANSPLANT

PATIENT STUDY I.D. NUMBER _____ 1 — — — — — — 6

DATE THIS FORM WAS COMPLETED _____ 7 — — — — — — 12

REFERRAL DATA

1. Was this patient referred to your program by an in-house physician, a physician outside your hospital, or was the patient self-referred (e.g., a drop-in)?

(CIRCLE ONE)

IN-HOUSE PHYSICIAN 01

OUTSIDE PHYSICIAN 02 13 14

SELF-REFERRED ..... 03 **(SKIP TO Q.4)**

2. If this patient was referred to your program by another physician, please provide the complete name, address, telephone number, and medical specialty of the referring physician.

_____
Physician's Full Name

_____
Institutional Affiliation 15 16

_____
Street Address 17 — — — — 21

_____
City State Zip Code

( )
_____
Area Code Telephone Number

3. _____ 22 23
Medical Specialty of Referring Physician

4. On what date was this patient initially referred to your heart transplant program for evaluation? (*PLEASE RECORD MONTH, DAY, AND YEAR.*)

/ /
_____
MONTH DAY YEAR 24 — — — — — 29

5. To your knowledge, was this patient previously evaluated by another heart transplant program?

(CIRCLE ONE)

YES 01

NO ..... 02 **(SKIP TO Q.8)**

DON'T KNOW ..... -2 **(SKIP TO Q.8)**

30 31

6. How many times has this patient been evaluated by a heart transplant program for purposes of receiving a heart transplant?

_____

NUMBER OF TIMES PATIENT HAS BEEN EVALUATED

32 33

7. At what other heart transplant programs was this patient evaluated before coming to your program? *(LIST ALL PROGRAMS BY NAME ONLY.)*

_____ 34 35

_____ — —

_____ 38 39

_____ — —

_____ 42 43

DEMOGRAPHIC AND PATIENT SELECTION DATA

8. What is this patient's birthdate?

_____ 44 — — — — — 49

MONTH DAY YEAR

9. Is this patient a male or female? *(CIRCLE ONE)*

MALE 01

FEMALE 02

50 51

10. What is this patient's race?

(CIRCLE ONE)

BLACK (NEGRO)	01
CHICANO (MEXICAN-AMERICAN)	02
NATIVE AMERICAN (AMERICAN INDIAN, ESKIMO, ALEUT)	03
WHITE (CAUCASIAN)	04
ORIENTAL (ASIAN AMERICAN OR PACIFIC ISLANDER)	05
OTHER	06
DON'T KNOW	-2

52 53

11. At the time of this patient's evaluation, what was his/her marital status?

(CIRCLE ONE)

SINGLE, NEVER MARRIED	01
MARRIED, SPOUSE PRESENT	02
MARRIED, SPOUSE ABSENT	03
SEPARATED	04
DIVORCED	05
WIDOWED	06
DON'T KNOW	-2

54 55

0 0 1

78 80

12. How many children were in the family?

NUMBER OF CHILDREN _____

(Dup 1-6)

7 8

13. What were the ages of the children?

13.1 CHILD 1	_____	13.6 CHILD 6	_____
13.2 CHILD 2	_____	13.7 CHILD 7	_____
13.3 CHILD 3	_____	13.8 CHILD 8	_____
13.4 CHILD 4	_____	13.9 CHILD 9	_____
13.5 CHILD 5	_____	13.10 CHILD 10	_____

14. What was this patient's employment status at the time of evaluation?

(CIRCLE ONE)

EMPLOYED FULL-TIME 01

EMPLOYED PART-TIME 02

EMPLOYED BUT TEMPORARILY LAID OFF 03

UNEMPLOYED, LOOKING FOR WORK 04

UNEMPLOYED, NOT LOOKING FOR WORK 05

UNABLE TO WORK
BECAUSE OF HEALTH (DISABLED) 06

HOMEMAKER 07

STUDENT (FULL-TIME) 08

RETIRED 09

OTHER (SPECIFY) _____ 10

DON'T KNOW ..... -2

15. Historically, which of the following would best describe this patient's employment status?

(CIRCLE ONE)

EMPLOYED FULL-TIME	01
EMPLOYED PART-TIME	02
EMPLOYED BUT TEMPORARILY LAID OFF	03
UNEMPLOYED, LOOKING FOR WORK	04
UNEMPLOYED, NOT LOOKING FOR WORK	05
UNABLE TO WORK BECAUSE OF HEALTH (DISABLED)	06
HOMEMAKER	07
STUDENT (FULL-TIME)	08
RETIRED	09
OTHER (SPECIFY) _____	10
DON'T KNOW	-2

31 32

16. Is this patient a U.S. citizen?

(CIRCLE ONE)

YES	01 **(SKIP TO Q.18)**
NO	02

33 34

17. What is this patient's country of residence?

_____

35 36 37

18. What was this patient's primary preoperative diagnosis at the time of his/her evaluation by your program?

(CIRCLE ONE)

CORONARY ARTERY DISEASE 01

IDIOPATHIC CARDIOMYOPATHY 02

VALVE DISEASE WITH CARDIOMYOPATHY 03

RHEUMATIC VALVULAR DISEASE 04

POSTTRAUMATIC ANEURYSM 05

CONGENITAL HEART DISEASE 06

CARDIAC TUMOR 07

OTHER (SPECIFY) _____ 08

19. What contraindications for heart transplantation, if any, did this patient exhibit? *(RECORD ALL CONTRAINDICATIONS. FOR ANY CONTRAINDICATIONS NOT LISTED, SPECIFY ON LINES PROVIDED.)*

(CIRCLE YES OR NO FOR EACH ITEM)

		YES	NO
19.1	SEVERE PULMONARY HYPERTENSION	01	02
19.2	IRREVERSIBLE AND SEVERE HEPATIC DYSFUNCTION	01	02
19.3	IRREVERSIBLE AND SEVERE RENAL DYSFUNCTION	01	02
19.4	ACTIVE SYSTEMIC INFECTION	01	02
19.5	OTHER SYSTEMIC DISEASE LIKELY TO LIMIT OR PRECLUDE SURVIVAL AND REHABILITATION AFTER TRANSPLANTATION.....	01	02
19.6	PSYCHIATRIC ILLNESS OR SEVERE BEHAVIORAL DISORDER	01	02
19.7	PHYSICAL HANDICAP	01	02
19.8	RECENT AND UNRESOLVED PULMONARY INFARCTION	01	02
19.9	INSULIN-REQUIRING DIABETES MELLITUS	01	02

38 39

78 **0 0 2** 80

(Dup 1-6)

7 8

11 12

15 16

19 20

23 24

	YES	NO	
19.10 SYMPTOMATIC OR DOCUMENTED SEVERE ASYMPTOMATIC PERIPHERAL OR CEREBROVASCULAR DISEASE	01	02	25 26
19.11 ACTIVE PEPTIC ULCER DISEASE	01	02	27 28
19.12 ABSENCE OF ADEQUATE EXTERNAL PSYCHOSOCIAL SUPPORT	01	02	
19.13 ADVANCING AGE (UNABLE TO WITHSTAND SURGERY OR POSTOPERATIVE COMPLICATIONS)	01	02	31 32
19.14 PULMONARY VASCULAR RESISTANCE **GREATER** THAN EIGHT WOOD UNITS	01	02	33 34
19.15 DRUG OR ALCOHOL ADDICTION	01	02	35 36
19.16 GOOD PROGNOSIS DESPITE CARDIAC DISEASE (BETTER THAN 10-25 PERCENT LIKELIHOOD OF SURVIVING FOR 6 MONTHS)	01	02	37 38
19.17 OTHER (SPECIFY) _____	01	02	39 40
19.18 OTHER (SPECIFY) _____	01	02	41 42
19.19 OTHER (SPECIFY) _____	01	02	43 44
19.20 OTHER (SPECIFY) _____	01	02	45 46

FUNCTIONAL STATUS DATA

20. At the time of evaluation, what was this patient's functional classification according to the New York Heart Classification?

(CIRCLE ONE)

CLASS I. Patients with cardiac disease but without resulting limitations of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain 01

CLASS II. Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain 02

CLASS III. Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary physical activity causes fatigue, palpitation, dyspnea, or anginal pain 03

CLASS IV. Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of cardiac insufficiency or of the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased 04

47 48

21. Please circle the number of the statement below which best describes this patient's functional status at the time of their evaluation.

(CIRCLE ONE)

NORMAL; NO COMPLAINTS; NO EVIDENCE OF DISEASE	01
ABLE TO CARRY ON NORMAL ACTIVITY; MINOR SIGNS AND SYMPTOMS OF DISEASE	02
NORMAL ACTIVITY WITH EFFORT; SOME SIGNS AND SYMPTOMS OF DISEASE	03
CARE FOR SELF; UNABLE TO CARRY ON NORMAL ACTIVITY OR DO ACTIVE WORK	04
REQUIRES OCCASIONAL ASSISTANCE BUT IS ABLE TO CARE FOR MOST OF OWN NEEDS	05
REQUIRES CONSIDERABLE ASSISTANCE AND FREQUENT MEDICAL CARE	06
DISABLED; REQUIRES SPECIAL CARE AND ASSISTANCE	07
SEVERELY DISABLED; HOSPITALIZATION IS INDICATED ALTHOUGH DEATH NOT IMMINENT	08
VERY SICK; HOSPITALIZATION NECESSARY	09
MORIBUND; FATAL PROCESSES PROGRESSING RAPIDLY	10
STATUS UNKNOWN	-2

49 50

FINANCIAL AND INSURANCE STATUS DATA

22. What was this patient's approximate yearly income at the time of evaluation?

$_____
YEARLY INCOME

51 57

23. Was this patient eligible for Medicare Part A, Medicare Part B, or both Medicare Part A and Part B benefits or neither at the time of evaluation?

(CIRCLE ONE)

MEDICARE PART A 01

MEDICARE PART B 02

BOTH MEDICARE PART A AND PART B 03

NOT ELIGIBLE FOR MEDICARE PART A OR B 04

DON'T KNOW ..... -2

58 59

24. Was this patient eligible for Medicaid benefits at the time of evaluation?

(CIRCLE ONE)

YES 01

NO 02

DON'T KNOW ..... -2

60 61

25. Did this patient have health insurance through a private insurer?

(CIRCLE ONE)

YES 01

NO ..... 02 **(SKIP TO Q.29)**

62 63

26. What was the name of the insurance company?

_____

NAME OF INSURER

64 67

78 **0** **0** **3** 80

27. Was the private insurer consulted concerning payment for heart transplantation?

(Dup 1-6)

(CIRCLE ONE)

YES 01

NO ..... 02 **(SKIP TO Q.29)**

DON'T KNOW ..... -2 **(SKIP TO Q.29)**

7 8

28. To your knowledge, did the patient's private insurer view heart transplantation as experimental or therapeutic?

(CIRCLE ONE)

EXPERIMENTAL 01

THERAPEUTIC 02

DON'T KNOW, NO DETERMINATION MADE . -2

9 10

29. Was this patient a veteran?

(CIRCLE ONE)

YES 01

NO ..... 02 **(SKIP TO Q.31)**

DON'T KNOW ..... -2 **(SKIP TO Q.31)**

11 12

30. Was he/she eligible for benefits under the CHAMPUS program?

(CIRCLE ONE)

YES 01

NO 02

DON'T KNOW ..... -2

13 14

EVALUATION PERIOD FINANCIAL DATA

31. Was this patient already hospitalized at your institution at the time of evaluation or was he/she admitted specifically for purposes of evaluation?

(CIRCLE ONE)

HOSPITALIZED BEFORE EVALUATION 01

HOSPITALIZED SPECIFICALLY FOR EVALUATION ..... 02 **(SKIP TO Q.33)**

15 16

32. On what date was the patient initially hospitalized?

_____/_____/_____
MONTH DAY YEAR

17 — — — — — 22

33. On what date did this patient's evaluation begin?

_____/_____/_____
MONTH DAY YEAR

23 — — — — — 28

34. How many days, if any, was this patient hospitalized at your institution in the ICU, CCU, and general ward during the **PRE-EVALUATION** period? Recall the **PRE-EVALUATION** period is the period between the dates specified in Q.32 and Q.33, above. *(IF THE PATIENT DID NOT HAVE A PRE-EVALUATION PERIOD, ZEROS SHOULD BE ENTERED ON ALL LINES.)*

ROOM	NUMBER OF DAYS
34.1 ICU (SURGICAL)	_____
34.2 ICU (OTHER)	_____
34.3 CCU	_____
34.4 GENERAL WARD (PRIVATE)	_____
34.5 GENERAL WARD (SEMI-PRIVATE)	_____
34.6 GENERAL WARD (OTHER)	_____
34.7 OTHER (SPECIFY) _____	_____

29 31 — — —

35 37 — — —

41 43 — — —

47 49 — — —

35. On what date did this patient's **EVALUATION** formally end?

_____ / _____ / _____
MONTH DAY YEAR

50 55 — — — — — —

36. On the basis of the **EVALUATION**, was this patient accepted or rejected as a heart transplant candidate?

(CIRCLE ONE)

ACCEPTED 01

REJECTED 02

56 57 — —

37. On what date was he/she accepted or rejected as a heart transplant candidate?

_____ / _____ / _____
MONTH DAY YEAR

58 63 — — — — — —

38. Is the date the evaluation began (see Question 33, above) between January 1, 1978 and June 30, 1983?

(CIRCLE ONE)

YES 01

NO ..... 02 **(SKIP TO Q. 44)**

64 65 — —

0 0 4
78 80

39. Charges for a patient's **EVALUATION** can be broken down into several categories including laboratory tests, diagnostic tests, drugs, medical and surgical supplies, room and board, and professional fees. Please provide a complete breakdown of charges for the **EVALUATION** period according to these major categories. Any items that do not fit these categories should be totaled and placed in the "other" category. Recall that the **EVALUATION** period is the period between the date on which the patient's **EVALUATION** began (see Q. 33, above) and the date on which the patient was accepted or rejected as a heart transplant candidate (see Q. 37, above).

ITEM OR SERVICE	CHARGE
A. MEDICAL, SURGICAL, AND CENTRAL SUPPLIES	(Dup 1-6)
A.1. MEDICAL SUPPLIES	$_____
A.2. SURGICAL SUPPLIES	$_____
A.3. CENTRAL SUPPLIES	$_____
A.4. OTHER SUPPLIES	$_____
A.5. TOTAL SUPPLIES (IF AVAILABLE)	$_____
B. OPERATING ROOM AND ANESTHESIA	
B.1. OPERATING ROOM	$_____
B.2. ANESTHESIA (EXCLUDING PROFESSIONAL TIME)	$_____
B.3. OTHER (SPECIFY) _____	$_____
B.4. TOTAL OPERATING ROOM AND ANESTHESIA (IF AVAILABLE)	$_____
C. PHARMACY	(Dup 1-6)
C.1. DRUGS, IN-HOSPITAL	$_____
C.2. DRUGS, TAKE-HOME OR DISCHARGE	$_____
C.3. I.V. SOLUTIONS	$_____
C.4. ALL OTHER DRUGS	$_____
C.5. TOTAL PHARMACY (IF AVAILABLE)	$_____

0 0 5

ITEM OR SERVICE (Continued)	CHARGE	
D. THERAPY		
D.1. RESPIRATORY/INHALATION THERAPY	$_____	33 — — — — 37
D.2. VOCATIONAL/OCCUPATIONAL THERAPY	$_____	— — — — —
D.3. PHYSICAL THERAPY/PHYSICAL MEDICINE	$_____	43 — — — — 47
D.4. OTHER THERAPY	$_____	— — — — —
D.5. TOTAL THERAPY (IF AVAILABLE)	$_____	53 — — — — 58
E. APPLIANCES	$_____	59 — — — — 64
		78 0 0 6 80
F. DIAGNOSTIC TESTS		(Dup 1-6)
F.1. EKG	$_____	7 — — — — 11
F.2. CARDIAC MONITORING/ CARDIAC CATH LAB	$_____	— — — — —
F.3. RADIOLOGY (X-RAY)	$_____	17 — — — — 21
F.4. RADIATION MEDICINE	$_____	— — — — —
F.5. NUCLEAR MEDICINE	$_____	27 — — — — 31
F.6. INFECTIOUS DISEASE	$_____	— — — — —
F.7. SURGICAL PATHOLOGY	$_____	37 — — — — 41
F.8. OTHER DIAGNOSTIC TESTS	$_____	— — — — —
F.9. TOTAL DIAGNOSTIC TESTS (IF AVAILABLE)	$_____	47 — — — — 52
		78 0 0 7 80

ITEM OR SERVICE (Continued)	CHARGE
G. BLOOD ADMINISTRATION	(Dup 1-6)
G.1. BLOOD TRANSFUSION	$_____
G.2. BLOOD BANK	$_____
G.3. COAGULATION LABORATORY	$_____
G.4. BLOOD PROCESSING	$_____
G.5. BLOOD PLASMA (PROC)	$_____
G.6. BLOOD ADMINISTRATION	$_____
G.7. BLOOD LAB	$_____
G.8. OTHER (SPECIFY) _____	$_____
G.9. TOTAL BLOOD AND ADMINISTRATION (IF AVAILABLE)	$_____
H. OXYGEN AND GAS MIXTURES	$_____

7 — 11
17 — 21
27 — 31
37 — 41
47 — 52
53 — 58
78 0 0 8 80

ITEM OR SERVICE (Continued)	CHARGE	(Dup 1-6)
I. LABORATORY TESTS		
I.1. HEMATOLOGY	$_____	7 — — — — 11
I.2. CHEMISTRY	$_____	— — — — —
I.3. IMMUNOLOGY/IMMUNOPATHOLOGY	$_____	17 — — — — 21
I.4. PULMONARY PHYSIOLOGY	$_____	— — — — —
I.5. VIROLOGY	$_____	27 — — — — 31
I.6. MICROBIOLOGY	$_____	— — — — —
I.7. DRUG ASSAY	$_____	37 — — — — 41
I.8. CLINICAL LABORATORY TESTS (IF GIVEN)	$_____	— — — — —
I.9. PATHOLOGY LAB TESTS (IF GIVEN)	$_____	47 — — — — 51
I.10. ICU LABORATORY TESTS	$_____	— — — — —
I.11. OTHER LABORATORY TESTS	$_____	57 — — — — 61
I.12. TOTAL LABORATORY TESTS (IF AVAILABLE)	$_____	62 — — — — 67
		0 0 9 78 80

ITEM OR SERVICE (Continued)	CHARGE
J. OTHER SERVICES	$_____
K. MISCELLANEOUS	$_____
L. PROFESSIONAL FEES	
L.1. ANESTHESIOLOGY	$_____
L.2. CARDIOLOGY	$_____
L.3. SURGERY	$_____
L.4. RADIOLOGY	$_____
L.5. PULMONARY PHYSICIAN	$_____
L.6. OCCUPATIONAL THERAPIST	$_____
L.7. OTHER (SPECIFY) _____	$_____
L.8. OTHER (SPECIFY) _____	$_____
L.9. OTHER (SPECIFY) _____	$_____
L.10. OTHER (SPECIFY) _____	$_____
L.11. TOTAL PROFESSIONAL FEES (IF AVAILABLE)	$_____
M. ROOM AND BOARD	
M.1. ICU (SURGICAL)	$_____
M.2. ICU (OTHER)	$_____
M.3. CCU	$_____
M.4. GENERAL WARD (PRIVATE)	$_____
M.5. GENERAL WARD (SEMI-PRIVATE)	$_____
M.6. GENERAL WARD (OTHER)	$_____
M.7. OTHER (SPECIFY) _____	$_____
M.8. TOTAL ROOM AND BOARD (IF AVAILABLE)	$_____
GRAND TOTAL	$_____

(Dup 1-6

(Dup 1-6

40. How many days did this patient spend in the ICU, CCU, and general ward during the **EVALUATION** period?

(Dup 1-6)

ROOM	NUMBER OF DAYS	
40.1 ICU (SURGICAL)	_____	7 — — 9
40.2 ICU (OTHER)	_____	— — —
40.3 CCU	_____	13 — — 15
40.4 GENERAL WARD (PRIVATE)	_____	— — —
40.5 GENERAL WARD (SEMI-PRIVATE)	_____	19 — — 21
40.6 GENERAL WARD (OTHER)	_____	— — —
40.7 OTHER (SPECIFY) _____	_____	25 — — 27

41. To whom were charges made for the care of this patient during the **EVALUATION** period?

a) Please indicate **all** sources of payment

(CIRCLE YES OR NO FOR EACH PAYMENT SOURCE)

		YES	NO	
41.1	SELF-PAY	01	02	28 29
41.2	OTHER FAMILY MEMBERS	01	02	30 31
41.3	MEDICARE	01	02	32 33
41.4	MEDICAID	01	02	34 35
41.5	CHAMPUS	01	02	36 37
41.6	OTHER GOVERNMENT PROGRAM	01	02	38 39
41.7	BLUE CROSS/BLUE SHIELD	01	02	40 41
41.8	OTHER PRIVATE OR COMMERCIAL INSURANCE	01	02	42 43
41.9	RESEARCH GRANT FUNDS (e.g., NIH)	01	02	44 45
41.10	SPECIAL PATIENT FUND	01	02	46 47
41.11	OTHER ANONYMOUS CONTRIBUTIONS	01	02	48 49
41.12	OTHER (SPECIFY)	01	02	50 51

b) Which of the above was the **principal** source of payment?

_____

PRINCIPAL SOURCE OF PAYMENT 52 53

42. What is the approximate dollar amount of charges paid by each source for the **EVALUATION** period?

		RECORD DOLLARS	
42. 1	SELF-PAY	$_____	54 _ _ _ _ _ _ 59
42. 2	OTHER FAMILY MEMBERS	$_____	_ _ _ _ _ _
42. 3	MEDICARE	$_____	66 _ _ _ _ _ _ 71
			78 **0 1 2** 80
			(Dup 1-6)
42. 4	MEDICAID	$_____	7 _ _ _ _ _ _ 12
42. 5	CHAMPUS	$_____	_ _ _ _ _ _
42. 6	OTHER GOVERNMENT PROGRAM	$_____	19 _ _ _ _ _ _ 24
42. 7	BLUE CROSS/BLUE SHIELD	$_____	_ _ _ _ _ _
42. 8	PRIVATE OR COMMERCIAL INSURANCE	$_____	31 _ _ _ _ _ _ 36
42. 9	RESEARCH GRANT FUNDS (e.g., NIH)	$_____	_ _ _ _ _ _
42.10	SPECIAL PATIENT FUND	$_____	43 _ _ _ _ _ _ 48
42.11	OTHER ANONYMOUS CONTRIBUTIONS	$_____	_ _ _ _ _ _
42.12	OTHER (SPECIFY)	$_____	55 _ _ _ _ _ _ 60

43. How much, if any, of this patient's hospital bill for **EVALUATION** was eventually written off by the hospital as bad debt?

BAD DEBT $ _____

☐ CHECK IF UNKNOWN

61 _ _ _ _ _ _ 66

78 **0 1 3** 80

44. On what date was this patient formally accepted into your program as a heart transplant candidate?

(Dup 1-6)

_____/_____/_____

MONTH DAY YEAR

7 — — — — — — 12

45. Was the patient accepted into your program as a heart transplant candidate (see question 44, above) between January 1, 1978 and June 30, 1983?

(CIRCLE ONE)

YES 01

NO ..... 02 **(SKIP TO Q. 51)**

13 — — 14

CANDIDACY PERIOD FINANCIAL DATA

46. Between the time a patient was accepted as a heart transplant candidate and the time of their transplant they may have incurred medical expenses. For this patient's **CANDIDACY** period, we would like you to assemble and summarize all data on medical expenses this patient may have incurred at your institution between the date he/she was accepted as a heart transplant candidate and the day before their transplant.

ITEM OR SERVICE	CHARGE
A. MEDICAL, SURGICAL, AND CENTRAL SUPPLIES	
A.1. MEDICAL SUPPLIES	$_____
A.2. SURGICAL SUPPLIES	$_____
A.3. CENTRAL SUPPLIES	$_____
A.4. OTHER SUPPLIES	$_____
A.5. TOTAL SUPPLIES (IF AVAILABLE)	$_____
B. OPERATING ROOM AND ANESTHESIA	
B.1. OPERATING ROOM	$_____
B.2. ANESTHESIA (EXCLUDING PROFESSIONAL TIME)	$_____
B.3. OTHER (SPECIFY)	$_____
B.4. TOTAL OPERATING ROOM AND ANESTHESIA (IF AVAILABLE)	$_____

15 19 — 25 29 — 35 40 — 46 50 — 56 61 — 0 1 4 78 80

ITEM OR SERVICE (Continued)	CHARGE	(Dup 1-6)
C. PHARMACY		
C.1. DRUGS, IN-HOSPITAL	$_____	7 — — — — 11
C.2. DRUGS, TAKE-HOME OR DISCHARGE	$_____	— — — — —
C.3. I.V. SOLUTIONS	$_____	17 — — — — 21
C.4. ALL OTHER DRUGS	$_____	— — — — —
C.5. TOTAL PHARMACY (IF AVAILABLE)	$_____	27 — — — — 32
D. THERAPY		
D.1. RESPIRATORY/INHALATION THERAPY	$_____	33 — — — — 37
D.2. VOCATIONAL/OCCUPATIONAL THERAPY	$_____	— — — — —
D.3. PHYSICAL THERAPY/PHYSICAL MEDICINE	$_____	43 — — — — 47
D.4. OTHER THERAPY	$_____	— — — — —
D.5. TOTAL THERAPY (IF AVAILABLE)	$_____	53 — — — — 58
E. APPLIANCES	$_____	59 — — — — 64
		78 **0 1 5** 80
F. DIAGNOSTIC TESTS		(Dup 1-6)
F.1. EKG	$_____	7 — — — — 11
F.2. CARDIAC MONITORING/ CARDIAC CATH LAB	$_____	— — — — —
F.3. RADIOLOGY (X-RAY)	$_____	17 — — — — 21
F.4. RADIATION MEDICINE	$_____	— — — — —
F.5. NUCLEAR MEDICINE	$_____	27 — — — — 31
F.6. INFECTIOUS DISEASE	$_____	— — — — —
F.7. SURGICAL PATHOLOGY	$_____	37 — — — — 41
F.8. OTHER DIAGNOSTIC TESTS	$_____	— — — — —
F.9. TOTAL DIAGNOSTIC TESTS (IF AVAILABLE)	$_____	47 — — — — 52
		78 **0 1 6** 80

ITEM OR SERVICE (Continued)	CHARGE	(Dup 1-6)
G. BLOOD ADMINISTRATION		
G.1. BLOOD TRANSFUSION	$_____	7 — — — — 11
G.2. BLOOD BANK	$_____	— — — — —
G.3. COAGULATION LABORATORY	$_____	17 — — — — 21
G.4. BLOOD PROCESSING	$_____	— — — — —
G.5. BLOOD PLASMA (PROC)	$_____	27 — — — — 31
G.6. BLOOD ADMINISTRATION	$_____	— — — — —
G.7. BLOOD LAB	$_____	37 — — — — 41
G.8. OTHER (SPECIFY)	$_____	— — — — —
G.9. TOTAL BLOOD AND ADMINISTRATION (IF AVAILABLE)	$_____	47 — — — — 52
H. OXYGEN AND GAS MIXTURES	$_____	53 — — — — 58
		78 **0** **1** **7** 80
I. LABORATORY TESTS		(Dup 1-6)
I.1. HEMATOLOGY	$_____	7 — — — — 11
I.2. CHEMISTRY	$_____	— — — — —
I.3. IMMUNOLOGY/IMMUNOPATHOLOGY	$_____	17 — — — — 21
I.4. PULMONARY PHYSIOLOGY	$_____	— — — — —
I.5. VIROLOGY	$_____	27 — — — — 31
I.6. MICROBIOLOGY	$_____	— — — — —
I.7. DRUG ASSAY	$_____	37 — — — — 41
I.8. CLINICAL LABORATORY TESTS (IF GIVEN)	$_____	— — — — —
I.9. PATHOLOGY LABORATORY TESTS (IF GIVEN)	$_____	47 — — — — 51
I.10. ICU LABORATORY TESTS	$_____	— — — — —
I.11. OTHER LABORATORY TESTS	$_____	57 — — — — 61
I.12. TOTAL LABORATORY TESTS (IF AVAILABLE)	$_____	62 — — — — 67
		78 **0** **1** **8** 80

ITEM OR SERVICE (Continued)	CHARGE	(Dup 1-6)
J. OTHER SERVICES	$_____	7 — — — — — 12
K. MISCELLANEOUS	$_____	13 — — — — — 18
L. PROFESSIONAL FEES		
L.1. ANESTHESIOLOGY	$_____	19 — — — — 23
L.2. CARDIOLOGY	$_____	— — — — —
L.3. SURGERY	$_____	29 — — — — 33
L.4. RADIOLOGY	$_____	— — — — —
L.5. PULMONARY PHYSICIAN	$_____	39 — — — — 43
L.6. OCCUPATIONAL THERAPIST	$_____	— — — — —
L.7. OTHER (SPECIFY) _____	$_____	49 — — — — 53
L.8. OTHER (SPECIFY) _____	$_____	— — — — —
L.9. OTHER (SPECIFY) _____	$_____	59 — — — — 63
L.10. OTHER (SPECIFY) _____	$_____	— — — — —
L.11. TOTAL PROFESSIONAL FEES (IF AVAILABLE)	$_____	69 — — — — — 74
		78 **0** **1** **9** 80
M. ROOM AND BOARD		(Dup 1-6)
M.1. ICU (SURGICAL)	$_____	7 — — — — 11
M.2. ICU (OTHER)	$_____	— — — — —
M.3. CCU	$_____	17 — — — — 21
M.4. GENERAL WARD (PRIVATE)	$_____	— — — — —
M.5. GENERAL WARD (SEMI-PRIVATE)	$_____	27 — — — — 31
M.6. GENERAL WARD (OTHER)	$_____	— — — — —
M.7. OTHER (SPECIFY) _____	$_____	37 — — — — 41
M.8. TOTAL ROOM AND BOARD (IF AVAILABLE)	$_____	42 — — — — — 47
GRAND TOTAL	$_____	48 — — — — — 53
		78 **0** **2** **0** 80

47. During the time this patient was awaiting a suitable donor heart, that is, the period **following their evaluation** up until the day before he/she received his/her heart transplant, how many days did he/she spend in the ICU, CCU, and general ward at your institution?

ROOM	NUMBER OF DAYS	(Dup 1-6)
47. 1 ICU (SURGICAL)	_____	___ 7 — ___ 9
47. 2 ICU (OTHER)	_____	— — —
47. 3 CCU	_____	___ 13 — ___ 15
47. 4 GENERAL WARD (PRIVATE)	_____	— — —
47. 5 GENERAL WARD (SEMI-PRIVATE)	_____	___ 19 — ___ 21
47. 6 GENERAL WARD (OTHER)	_____	— — —
47. 7 OTHER (SPECIFY) _____	_____	___ 25 — ___ 27

48. To whom were charges made for the care of this patient during this period?

a) Please indicate **all** sources of payment

(CIRCLE YES OR NO FOR EACH PAYMENT SOURCE)

		YES	NO	
48. 1	SELF-PAY	01	02	28 29
48. 2	OTHER FAMILY MEMBERS	01	02	30 31
48. 3	MEDICARE	01	02	32 33
48. 4	MEDICAID	01	02	34 35
48. 5	CHAMPUS	01	02	36 37
48. 6	OTHER GOVERNMENT PROGRAM	01	02	38 39
48. 7	BLUE CROSS/BLUE SHIELD	01	02	40 41
48. 8	OTHER PRIVATE OR COMMERCIAL INSURANCE	01	02	42 43
48. 9	RESEARCH GRANT FUNDS (e.g., NIH)	01	02	44 45
48.10	SPECIAL PATIENT FUND	01	02	46 47
48.11	OTHER ANONYMOUS CONTRIBUTIONS	01	02	48 49
48.12	OTHER (SPECIFY) _____	01	02	50 51

b) Which of the above was the principal source of payment?

_____

PRINCIPAL SOURCE OF PAYMENT 52 53

49. What is the approximate dollar amount of charges paid by each source for the period?

		RECORD DOLLARS
49. 1	SELF-PAY	$_____
49. 2	OTHER FAMILY MEMBERS	$_____
49. 3	MEDICARE	$_____
49. 4	MEDICAID	$_____
49. 5	CHAMPUS	$_____
49. 6	OTHER GOVERNMENT PROGRAM	$_____
49. 7	BLUE CROSS/BLUE SHIELD	$_____
49. 8	PRIVATE OR COMM. INSURANCE	$_____
49. 9	RESEARCH GRANT FUNDS (e.g., NIH)	$_____
49.10	SPECIAL PATIENT FUND	$_____
49.11	OTHER ANONYMOUS CONTRIBUTIONS	$_____
49.12	OTHER (SPECIFY) _____	$_____

54 59
66 71
78 0 2 1 80
(Dup 1-6)
7 12
19 24
31 36
43 48
55 60

50. How much, if any, of this patient's hospital bill for the **CANDIDACY** period was eventually written off by the hospital as bad debt?

BAD DEBT $ _____

☐ CHECK IF UNKNOWN

61 66
78 0 2 2 80
(Dup 1-6)

51. Has this patient had more than one heart transplant?

(CIRCLE ONE)

YES 01

NO ..... 02 **(SKIP TO Q.54)**

7 8

52. How many heart transplants has he/she had?

_____
NUMBER OF HEART TRANSPLANTS

9 10

53. On what dates did he/she receive each retransplant and what was the primary reason for retransplantation?

HEART RETRANSPLANT NUMBER	DATE OF TRANSPLANT	PRIMARY REASON FOR RETRANSPLANTATION
1	/ /	
2	/ /	
3	/ /	
4	/ /	
5	/ /	

11 — — — — — — 16

17 18

19 — — — — — — 24

25 26

54. Was this patient's (most recent) heart transplant orthotopic or heterotopic?

(CIRCLE ONE)

ORTHOTOPIC 01

HETEROTOPIC 02

27 28

55. Please check the statement below which best describes this patient's condition at the time just before he/she received the most recent heart transplant.

(CIRCLE ONE)

NORMAL; NO COMPLAINTS; NO EVIDENCE OF DISEASE 01

ABLE TO CARRY ON NORMAL ACTIVITY: MINOR SIGNS AND SYMPTOMS OF DISEASE 02

NORMAL ACTIVITY WITH EFFORT; SOME SIGNS AND SYMPTOMS OF DISEASE 03

CARE FOR SELF; UNABLE TO CARRY ON NORMAL ACTIVITY OR DO ACTIVE WORK 04

REQUIRES OCCASIONAL ASSISTANCE BUT IS ABLE TO CARE FOR MOST OF OWN NEEDS 05

REQUIRES CONSIDERABLE ASSISTANCE AND FREQUENT MEDICAL CARE 06

DISABLED; REQUIRES SPECIAL CARE AND ASSISTANCE 07

SEVERELY DISABLED; HOSPITALIZATION IS INDICATED ALTHOUGH DEATH NOT IMMINENT 08

VERY SICK; HOSPITALIZATION NECESSARY 09

MORIBUND; FATAL PROCESSES PROGRESSING RAPIDLY 10

29 30

56. Which, if any, of the following conditions did this patient have before their transplant and which do they have at this time or at the time of their death? *(CIRCLE BOTH IF THE PATIENT IS KNOWN TO HAVE HAD THE CONDITION BOTH BEFORE TRANSPLANTATION AND NOW OR AT THE TIME OF DEATH.)*

(CIRCLE ONE RESPONSE FOR EACH CONDITION)

		NEVER	BEFORE TRANSPLANT	NOW OR AT TIME OF DEATH	BOTH	
56. 1	CANCER	01	02	03	04	31 32
56. 2	CHRONIC LUNG DISORDER	01	02	03	04	
56. 3	STOMACH ULCER	01	02	03	04	35 36
56. 4	CHRONIC KIDNEY DISORDER	01	02	03	04	
56. 5	DIABETES	01	02	03	04	39 40
56. 6	EPILEPTIC SEIZURES OR CONVULSIONS	01	02	03	04	
56. 7	OSTEOPOROSIS OR OTHER BONE DISEASE	01	02	03	04	43 44
56. 8	BACK OR SPINE DISORDER	01	02	03	04	
56. 9	VISION (SIGHT) DISORDER	01	02	03	04	47 48
56.10	NERVOUS OR EMOTIONAL PROBLEMS	01	02	03	04	
56.11	MENTAL DISORDER	01	02	03	04	51 52
56.12	ALCOHOL OR DRUG PROBLEMS	01	02	03	04	
56.13	SLEEP DISORDER	01	02	03	04	55 56

HISTOCOMPATIBILITY

57. Due to the complexity of histocompatibility testing and our desire not to omit important data, we would like you to record all histocompatibility findings as they pertain to this case (e.g., number of HLA-B mismatches, ABO blood type compatibility, negativity of lymphocyte crossmatch, etc.).

57 58

61 62

67 68

0 2 3
78 80

DONOR HEART PROCUREMENT DATA

The following data are being requested concerning the heart donor. These data include characteristics of the donor, aspects of managing the donor, and the logistics of transporting the donor or the heart.

(Dup 1-6)

58. What was the heart donor's age?

_____
AGE IN YEARS

7 8

59. What was the donor's sex?

(CIRCLE ONE)

MALE 01

FEMALE 02

DON'T KNOW ..... -2

9 10

60. What was the donor's race?

(CIRCLE ONE)

BLACK (NEGRO) 01

CHICANO (MEXICAN-AMERICAN) 02

NATIVE AMERICAN
(AMERICAN INDIAN, ESKIMO, ALEUT) 03

WHITE (CAUCASIAN) 04

ORIENTAL (ASIAN AMERICAN
OR PACIFIC ISLANDER) 05

OTHER 06

DON'T KNOW ..... -2

11 12

61. What was the donor's ABO blood type?

_____
BLOOD TYPE

13 14

62. What was the donor's primary cause of death?

(CIRCLE ONE)

BLUNT HEAD TRAUMA 01

CEREBROVASCULAR ACCIDENT 02

GUNSHOT WOUND 03

OTHER (SPECIFY) _____ ... 04

DON'T KNOW ..... -2

15 16

63. Which, if any, of the following drugs were used during life support after declaration of brain death of the donor?

(CIRCLE YES OR NO FOR EACH ITEM)

		YES	NO	
63. 1	VASOPRESSORS	01	02	17 18
63. 2	ANTIBIOTICS	01	02	— —
63. 3	STEROIDS	01	02	21 22
63. 4	AZATHIOPRINE	01	02	— —
63. 5	OTHER (SPECIFY) _____ ...	01	02	25 26
63. 6	OTHER (SPECIFY) _____ ...	01	02	— —
63. 7	OTHER (SPECIFY) _____ ...	01	02	29 30
63. 8	OTHER (SPECIFY) _____ ...	01	02	— —
63. 9	OTHER (SPECIFY) _____ ...	01	02	— —
63.10	OTHER (SPECIFY) _____ ...	01	02	35 36

64. Was cardioplegia used? *(CIRCLE ONE)*

YES 01

NO 02

DON'T KNOW ..... -2

37 38

65. What was the ischemic time for the donor heart?

_____ HOURS AND _____ MINUTES

39 — 41

66. Was the donor a multiple organ donor?

(CIRCLE ONE)

YES 01

NO ..... 02 **(SKIP TO Q.68)**

DON'T KNOW ..... -2 **(SKIP TO Q.68)**

67. What other organs or tissues were removed?

(CHECK YES OR NO FOR EACH ITEM)

		YES	NO
67. 1	KIDNEYS	01	02
67. 2	CORNEAS	01	02
67. 3	LIVER	01	02
67. 4	LUNGS	01	02
67. 5	PANCREAS	01	02
67. 6	SKIN	01	02
67. 7	OTHER (SPECIFY) _____	01	02

68. What was the primary mode of transport for the donor heart?

(CIRCLE ONE)

AIRCRAFT 01

AMBULANCE 02

ON-SITE RETRIEVAL 03

OTHER (SPECIFY) _____ 04

DON'T KNOW ..... -2

69. Was the donor or just the heart transported to your transplant center?

(CIRCLE ONE)

DONOR 01

HEART ONLY 02

DON'T KNOW ..... -2

42 43

44 45

48 49

52 53

56 57

58 59

60 61

78 **0** **2** **4** 80

IMMUNOSUPPRESSION PROTOCOLS

70. Which of the following immunosuppressive drugs were prescribed for this patient immediately (within 12 hours) after their heart transplant surgery? (Dup 1-6)

(CIRCLE YES OR NO FOR EACH ITEM)

		YES	NO	
70. 1	HORSE ATG	01	02	7 8
70. 2	RABBIT ATG	01	02	— —
70. 3	OTHER ATG	01	02	11 12
70. 4	METHYLPREDNISOLONE	01	02	— —
70. 5	AZATHIOPRINE	01	02	15 16
70. 6	PREDNISONE	01	02	— —
70. 7	CYCLOPHOSPHAMIDE	01	02	19 20
70. 8	CYCLOSPORIN-A	01	02	— —
70. 9	OTHER (SPECIFY) _____	01	02	— —
70.10	OTHER (SPECIFY) _____	01	02	25 26

71. Which of the following immunosuppressive drugs were prescribed for this patient at the time of their initial discharge from the hospital following their heart transplant surgery?

(CIRCLE YES OR NO FOR EACH ITEM)

		YES	NO	
71.1	AZATHIOPRINE	01	02	27 28
71.2	PREDNISONE	01	02	— —
71.3	CYCLOPHOSPHAMIDE	01	02	31 32
71.4	CYCLOSPORIN-A	01	02	— —
71.5	OTHER (SPECIFY) _____	01	02	35 36
71.6	OTHER (SPECIFY) _____	01	02	— —
71.7	OTHER (SPECIFY) _____	01	02	— —
71.8	PATIENT EXPIRED PRIOR TO DISCHARGE	01	02	41 42

72. Which of the following immunosuppressive drugs are currently prescribed for this patient or were prescribed for the patient at the time of his/her death? *(IF THE PATIENT WAS BEING TREATED FOR REJECTION AT THE TIME OF DEATH, RECORD THE DRUGS HE/SHE WAS ON JUST BEFORE REJECTION OCCURRED.)*

(CIRCLE YES OR NO FOR EACH ITEM)

		YES	NO	
72.1	AZATHIOPRINE	01	02	43 44
72.2	PREDNISONE	01	02	
72.3	CYCLOPHOSPHAMIDE	01	02	47 48
72.4	CYCLOSPORIN-A	01	02	
72.5	OTHER (SPECIFY)	01	02	51 52
72.6	OTHER (SPECIFY)	01	02	
72.7	OTHER (SPECIFY)	01	02	
72.8	OTHER (SPECIFY)	01	02	57 58

73. For purposes of immunosuppression, did this patient receive total lymphnoid irridiation or have thoracic duct drainage performed in conjunction with their most recent transplant?

(CIRCLE YES OR NO FOR EACH ITEM)

		YES	NO	
73.1	TOTAL LYMPHOID IRRADIATION	01	02	59 60
73.2	THORACIC DUCT DRAINAGE	01	02	61 62

HOSPITALIZATION HISTORY

74. We would also like to obtain data on this patient's complete hospitalization history at your hospital since their initial **DISCHARGE** from the hospital following transplantation. We are interested in the dates of hospitalization, the number of days the patient was hospitalized for each episode, and the primary reason for hospitalization. If the patient expired before being discharged, or was never hospitalized, please place a check in the box provided below.

☐ PATIENT NOT HOSPITALIZED

HOSPITAL STAY	DATES OF HOSPITALIZATION FROM	TO	NUMBER OF DAYS HOSPITALIZED	PRIMARY REASON FOR HOSPITALIZATION
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				

(Dup 1-6)

7 — — — — 11
— — — — —
17 — — — — 21
— — — — —
27 — — — — 31
— — — — —
37 — — — — 41
— — — — —
47 — — — — 51
— — — — —
57 — — — — 61
— — — — —
— — — — —
72 — — — — 76
0 2 6
78 80

(Dup 1-6)

7 — — — — 11
— — — — —
17 — — — — 21

HOSPITAL STAY	DATES OF HOSPITALIZATION FROM	TO	NUMBER OF DAYS HOSPITALIZED	PRIMARY REASON FOR HOSPITALIZATION
20				
21				
22				
23				
24				
25				
26				
27				
28				
29				
30				
31				
32				
33				
34				
35				
36				
37				
38				
39				
40				
41				
42				
43				
44				
45				

22 — 26

27 — 31

37 — 41

47 — 51

57 — 61

72 — 76

0 2 7

78 — 80

HOSPITAL STAY	DATES OF HOSPITALIZATION FROM	TO	NUMBER OF DAYS HOSPITALIZED	PRIMARY REASON FOR HOSPITALIZATION
46				
47				
48				
49				
50				
51				
52				
53				
54				
55				
56				
57				
58				
59				
60				
61				
62				
63				
64				
65				

INFECTION HISTORY

75. We would also like to obtain data on this patient's postoperative history of infections. We are interested in the date on which the infection was diagnosed and the type of infection. If the patient expired before having an episode of infection, or never had an episode of infection, please place a check in the box provided below.

☐ PATIENT WITHOUT AN EPISODE OF INFECTION

INFECTION EPISODE	DATE INFECTION WAS DIAGNOSED	TYPE OF INFECTION
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
11		
12		
13		
14		
15		
16		
17		
18		

(Dup 1-6)

7 8

11 12

15 16

19 20

23 24

27 28

31 32

35 36

41 42

INFECTION EPISODE	DATE INFECTION WAS DIAGNOSED	TYPE OF INFECTION
19		
20		
21		
22		
23		
24		
25		
26		
27		
28		
29		
30		
31		
32		
33		
34		
35		
36		
37		
38		
39		
40		
41		
42		

43 44

47 48

51 52

55 56

59 60

63 64

67 68

71 72

75 76

0 2 8
78 80

INFECTION EPISODE	DATE INFECTION WAS DIAGNOSED	TYPE OF INFECTION
43		
44		
45		
46		
47		
48		
49		
50		
51		
52		
53		
54		
55		
56		
57		
58		
59		
60		
61		
62		
63		
64		
65		

REJECTION HISTORY

76. We would also like to obtain data on this patient's history of postoperative rejections. We are interested in the date on which each rejection episode was first diagnosed. Each date should signify a new rejection episode. If the patient expired before having a rejection episode, or never had an episode of rejection, please place a check in the box provided below.

☐ PATIENT WITHOUT A REJECTION EPISODE

REJECTION EPISODE	DATE DIAGNOSIS CONFIRMED
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	
12	
13	
14	
15	
16	
17	
18	
19	
20	
21	

(Dup 1-6)

7 8

REJECTION EPISODE	DATE DIAGNOSIS CONFIRMED
22	
23	
24	
25	
26	
27	
28	
29	
30	
31	
32	
33	
34	
35	
36	
37	
38	
39	
40	
41	
42	
43	
44	
45	
46	
47	

REJECTION EPISODE	DATE DIAGNOSIS CONFIRMED
48	
49	
50	
51	
52	
53	
54	
55	
56	
57	
58	
59	
60	
61	
62	
63	
64	
65	
66	
67	
68	
69	
70	

TRANSPLANTATION PERIOD FINANCIAL DATA

77. On what date did this patient receive his/her heart transplant?

_____/_____/_____
MONTH DAY YEAR

9 — — — — — 14

78. On what date was this patient discharged from the hospital after having his/her heart transplant operation? *(IF THE PATIENT EXPIRED WHILE HOSPITALIZED FOR THE TRANSPLANT, RECORD THEIR DATE OF DEATH AND PLACE A CHECK IN THE BOX PROVIDED BELOW THE DATE.)*

_____/_____/_____
MONTH DAY YEAR

15 — — — — — 20

☐ PATIENT EXPIRED PRIOR TO DISCHARGE

79. During the **TRANSPLANTATION** period, that is, the period between the day the patient received his/her heart transplant (see Q. 77, above) and the date on which the patient was discharged from the hospital or expired before being discharged (see Q. 78, above) how many days did he/she spend in the ICU, CCU, and the general ward at your institution?

	ROOM	NUMBER OF DAYS	
79.1	ICU (SURGICAL)	_____	21 — 23
79.2	ICU (OTHER)	_____	— — —
79.3	CCU	_____	27 — 29
79.4	GENERAL WARD (PRIVATE)	_____	— — —
79.5	GENERAL WARD (SEMI-PRIVATE)	_____	33 — 35
79.6	GENERAL WARD (OTHER)	_____	— — —
79.7	OTHER (SPECIFY)_____	_____	39 — 41

80. Is the date of the heart transplant (see Question 77, above) between January 1, 1978 and June 30, 1983?

(CIRCLE ONE)

YES 01

NO ..... 02 **(SKIP TO Q.88)**

42 — 43

0 2 9
78 — 80

81. Charges for a patient's heart transplantation (i.e., the **TRANSPLANTATION** period), excluding the procurement of the donor heart, can be broken down into several categories including laboratory tests, diagnostic tests, pharmacy, medical, surgical, and central supplies, blood administration, operating room and anesthesia, room and board, professional fees, and so forth. Please provide a complete breakdown of charges for this patient's transplantation operation according to the categories provided below. If your billing does not break out specific items that are listed, total them and place them under the "other" category. Recall that the **TRANSPLANTATION** period is the period between the date the patient received his/her transplant (see Q. 77 above) and the date of his/her initial discharge from the hospital following transplant surgery, or the date the patient expired if this occurred prior to initial discharge (see Q. 78 above).

ITEM OR SERVICE	CHARGE
A. MEDICAL, SURGICAL, AND CENTRAL SUPPLIES	
A.1. MEDICAL SUPPLIES	$_____
A.2. SURGICAL SUPPLIES	$_____
A.3. CENTRAL SUPPLIES	$_____
A.4. OTHER SUPPLIES	$_____
A.5. TOTAL SUPPLIES (IF AVAILABLE)	$_____
B. OPERATING ROOM AND ANESTHESIA	
B.1. OPERATING ROOM	$_____
B.2. ANESTHESIA (EXCLUDING PROFESSIONAL TIME)	$_____
B.3. OTHER (SPECIFY) _____	$_____
B.4. TOTAL OPERATING ROOM AND ANESTHESIA (IF AVAILABLE)	$_____

(Dup 1-6)

7 — — — — 11

— — — — —

17 — — — — 21

— — — — —

27 — — — — — 32

— — — — —

38 — — — — 42

— — — — —

48 — — — — — 53

0 3 0

78 80

ITEM OR SERVICE (Continued)	CHARGE	
C. PHARMACY		(Dup 1-6)
C.1. DRUGS, IN-HOSPITAL	$_____	7 — — — — 11
C.2. DRUGS, TAKE-HOME OR DISCHARGE	$_____	— — — — —
C.3. I.V. SOLUTIONS	$_____	17 — — — — 21
C.4. ALL OTHER DRUGS	$_____	— — — — —
C.5. TOTAL PHARMACY (IF AVAILABLE)	$_____	27 — — — — 32
D. THERAPY		
D.1. RESPIRATORY/INHALATION THERAPY	$_____	33 — — — — 37
D.2. VOCATIONAL/OCCUPATIONAL THERAPY	$_____	— — — — —
D.3. PHYSICAL THERAPY/PHYSICAL MEDICINE	$_____	43 — — — — 47
D.4. OTHER THERAPY	$_____	— — — — —
D.5. TOTAL THERAPY (IF AVAILABLE)	$_____	53 — — — — 58
E. APPLIANCES	$_____	59 — — — — 64
		78 **0** **3** **1** 80
F. DIAGNOSTIC TESTS		(Dup 1-6)
F.1. EKG	$_____	7 — — — — 11
F.2. CARDIAC MONITORING/ CARDIAC CATH LAB	$_____	— — — — —
F.3. RADIOLOGY (X-RAY)	$_____	17 — — — — 21
F.4. RADIATION MEDICINE	$_____	— — — — —
F.5. NUCLEAR MEDICINE	$_____	27 — — — — 31
F.6. INFECTIOUS DISEASE	$_____	— — — — —
F.7. SURGICAL PATHOLOGY	$_____	37 — — — — 41
F.8. OTHER DIAGNOSTIC TESTS	$_____	— — — — —
F.9. TOTAL DIAGNOSTIC TESTS (IF AVAILABLE)	$_____	47 — — — — 52

78 **0** **3** **2** 80

ITEM OR SERVICE (Continued)	CHARGE	(Dup 1-6)
G. BLOOD ADMINISTRATION		
G.1. BLOOD TRANSFUSION	$_____	
G.2. BLOOD BANK	$_____	
G.3. COAGULATION LABORATORY	$_____	
G.4. BLOOD PROCESSING	$_____	
G.5. BLOOD PLASMA (PROC)	$_____	
G.6. BLOOD ADMINISTRATION	$_____	
G.7. BLOOD LAB	$_____	
G.8. OTHER (SPECIFY)	$_____	
G.9. TOTAL BLOOD AND ADMINISTRATION (IF AVAILABLE)	$_____	
H. OXYGEN AND GAS MIXTURES	$_____	
I. LABORATORY TESTS		033
		(Dup 1-6)
I.1. HEMATOLOGY	$_____	
I.2. CHEMISTRY	$_____	
I.3. IMMUNOLOGY/IMMUNOPATHOLOGY	$_____	
I.4. PULMONARY PHYSIOLOGY	$_____	
I.5. VIROLOGY	$_____	
I.6. MICROBIOLOGY	$_____	
I.7. DRUG ASSAY	$_____	
I.8. CLINICAL LABORATORY TESTS (IF GIVEN)	$_____	
I.9. PATHOLOGY LABORATORY TESTS (IF GIVEN)	$_____	
I.10. ICU LABORATORY TESTS	$_____	
I.11. OTHER LABORATORY TESTS	$_____	
I.12. TOTAL LABORATORY TESTS (IF AVAILABLE)	$_____	

034

ITEM OR SERVICE (Continued)	CHARGE	(Dup 1-6)
J. OTHER SERVICES	$_____	7 — — — — — 12
K. MISCELLANEOUS	$_____	13 — — — — — 18
L. PROFESSIONAL FEES		
L.1. ANESTHESIOLOGY	$_____	19 — — — — — 23
L.2. CARDIOLOGY	$_____	— — — — —
L.3. SURGERY	$_____	29 — — — — — 33
L.4. RADIOLOGY	$_____	— — — — —
L.5. PULMONARY PHYSICIAN	$_____	39 — — — — — 43
L.6. OCCUPATIONAL THERAPIST	$_____	— — — — —
L.7. OTHER (SPECIFY) _____	$_____	49 — — — — — 53
L.8. OTHER (SPECIFY) _____	$_____	— — — — —
L.9. OTHER (SPECIFY) _____	$_____	59 — — — — — 63
L.10. OTHER (SPECIFY) _____	$_____	— — — — —
L.11. TOTAL PROFESSIONAL FEES (IF AVAILABLE)	$_____	69 — — — — — 74
		0 3 5 78 80

ITEM OR SERVICE (Continued)	CHARGE	
M. ROOM AND BOARD		(Dup 1-6)
M.1. ICU (SURGICAL)	$_____	7 — 11
M.2. ICU (OTHER)	$_____	— — — — —
M.3. CCU	$_____	17 — 21
M.4. GENERAL WARD (PRIVATE)	$_____	— — — — —
M.5. GENERAL WARD (SEMI-PRIVATE)	$_____	27 — 31
M.6. GENERAL WARD (OTHER)	$_____	— — — — —
M.7. OTHER (SPECIFY) _____	$_____	37 — 41
M.8. TOTAL ROOM AND BOARD (IF AVAILABLE)	$_____	42 — 47
N. HISTOCOMPATIBILITY TESTING (RECIPIENT ONLY)	$_____	48 — 53
O. DONOR HEART ACQUISITION CHARGE (ALSO SEE Q.85)	$_____	— — — — — —
GRAND TOTAL	$_____	60 — 65
		0 3 6 (78 — 80)

82. To whom were charges made for the care of this patient during the **TRANSPLANTATION** period?

a) Please indicate **all** sources of payment

(CIRCLE YES OR NO FOR EACH PAYMENT SOURCE)

(Dup 1-6)

		YES	NO	
82. 1	SELF-PAY	01	02	7 8
82. 2	OTHER FAMILY MEMBERS	01	02	
82. 3	MEDICARE	01	02	11 12
82. 4	MEDICAID	01	02	
82. 5	CHAMPUS	01	02	15 16
82. 6	OTHER GOVERNMENT PROGRAM	01	02	
82. 7	BLUE CROSS/BLUE SHIELD	01	02	19 20
82. 8	OTHER PRIVATE OR COMMERCIAL INSURANCE	01	02	
82. 9	RESEARCH GRANT FUNDS (e.g., NIH)	01	02	23 24
82.10	SPECIAL PATIENT FUND	01	02	
82.11	OTHER ANONYMOUS CONTRIBUTIONS	01	02	
82.12	OTHER (SPECIFY) _____	01	02	29 30

b) Which of the above was the **principal** source of payment?

_____

PRINCIPAL SOURCE OF PAYMENT

31 32

83. What is the approximate dollar amount of charges paid by each source for the heart transplant?

		RECORD DOLLARS
83.1	SELF-PAY	$_____
83.2	OTHER FAMILY MEMBERS	$_____
83.3	MEDICARE	$_____
83.4	MEDICAID	$_____
83.5	CHAMPUS	$_____
83.6	OTHER U.S. GOVERNMENT PROGRAM	$_____
83.7	BLUE CROSS/BLUE SHIELD	$_____
83.8	PRIVATE OR COMMERCIAL INSURANCE	$_____
83.9	RESEARCH GRANT FUNDS (e.g., NIH)	$_____
83.10	SPECIAL PATIENT FUND	$_____
83.11	ANONYMOUS CONTRIBUTIONS	$_____
83.12	OTHER (SPECIFY)_____	$_____

84. How much, if any, of this patient's hospital bill for transplantation was eventually written off by the hospital as bad debt?

BAD DEBT $ _____

☐ CHECK IF UNKNOWN

0 3 7

(Dup 1-6)

0 3 8

ORGAN PROCUREMENT FINANCIAL DATA

85. Charges for the donor heart can be broken down into several categories; laboratory tests, diagnostic tests, pharmacy, medical, surgical, and central supplies, blood administration, operating room and anesthesia, room and board, professional fees, transportation, and so forth. Please provide a complete breakdown of charges for the donor heart according to the categories provided below. If your billing does not breakout specific items that are listed, total them and place them under the "other" category. If a flat fee was charged for the donor heart and charges cannot be broken out separately, check the box provided below and indicate the amount paid on the line next to it.

(Dup 1-6)

☐ FLAT FEE OF $_____ PAID FOR DONOR HEART

ITEM OR SERVICE	CHARGE
A. MEDICAL, SURGICAL, AND CENTRAL SUPPLIES	
A.1. MEDICAL SUPPLIES	$_____
A.2. SURGICAL SUPPLIES	$_____
A.3. CENTRAL SUPPLIES	$_____
A.4. OTHER SUPPLIES	$_____
A.5. TOTAL SUPPLIES (IF AVAILABLE)	$_____
B. OPERATING ROOM AND ANESTHESIA	
B.1. OPERATING ROOM	$_____
B.2. ANESTHESIA (EXCLUDING PROFESSIONAL TIME)	$_____
B.3. OTHER (SPECIFY) _____	$_____
B.4. TOTAL OPERATING ROOM AND ANESTHESIA (IF AVAILABLE)	$_____

0 3 9

(Dup 1-6)

C. PHARMACY	
C.1. DRUGS, IN-HOSPITAL	$_____
C.2. DRUGS, TAKE-HOME OR DISCHARGE	$_____
C.3. IV SOLUTIONS	$_____
C.4. ALL OTHER DRUGS	$_____
C.5. TOTAL PHARMACY (IF AVAILABLE)	$_____

ITEM OR SERVICE (Continued)	CHARGE	
D. THERAPY		
D.1. RESPIRATORY/INHALATION THERAPY	$_____	33 37
D.2. VOCATIONAL/OCCUPATIONAL THERAPY	$_____	
D.3. PHYSICAL THERAPY/PHYSICAL MEDICINE	$_____	43 47
D.4. OTHER THERAPY	$_____	
D.5. TOTAL THERAPY (IF AVAILABLE)	$_____	53 58
E. APPLIANCES	$_____	59 64
		78 **0** **4** **0** 80
F. DIAGNOSTIC TESTS		(Dup 1-6)
F.1. EKG	$_____	7 11
F.2. CARDIAC MONITORING/ CARDIAC CATH LAB	$_____	
F.3. RADIOLOGY (X-RAY)	$_____	17 21
F.4. RADIATION MEDICINE	$_____	
F.5. NUCLEAR MEDICINE	$_____	27 31
F.6. INFECTIOUS DISEASE	$_____	
F.7. SURGICAL PATHOLOGY	$_____	37 41
F.8. OTHER DIAGNOSTIC TESTS	$_____	
F.9. TOTAL DIAGNOSTIC TESTS (IF AVAILABLE)	$_____	47 52
		78 **0** **4** **1** 80

ITEM OR SERVICE (Continued)	CHARGE	(Dup 1-6)
G. BLOOD ADMINISTRATION		
G.1. BLOOD TRANSFUSION	$_____	7 11
G.2. BLOOD BANK	$_____	
G.3. COAGULATION LABORATORY	$_____	17 21
G.4. BLOOD PROCESSING	$_____	
G.5. BLOOD PLASMA (PROC)	$_____	27 31
G.6. BLOOD ADMINISTRATION	$_____	
G.7. BLOOD LAB	$_____	37 41
G.8. OTHER (SPECIFY)	$_____	
G.9. TOTAL BLOOD AND ADMINISTRATION (IF AVAILABLE)	$_____	47 52
H. OXYGEN AND GAS MIXTURES	$_____	53 58
		78 0 4 2 80
I. LABORATORY TESTS		(Dup 1-6)
I.1. HEMATOLOGY	$_____	7 11
I.2. CHEMISTRY	$_____	
I.3. IMMUNOLOGY/IMMUNOPATHOLOGY	$_____	17 21
I.4. PULMONARY PHYSIOLOGY	$_____	
I.5. VIROLOGY	$_____	27 31
I.6. MICROBIOLOGY	$_____	
I.7. DRUG ASSAY	$_____	37 41
I.8. CLINICAL LABORATORY TESTS (IF GIVEN)	$_____	
I.9. PATHOLOGY LABORATORY TESTS (IF GIVEN)	$_____	47 51
I.10. ICU LABORATORY TESTS	$_____	
I.11. OTHER LABORATORY TESTS	$_____	57 61
I.12. TOTAL LABORATORY TESTS (IF AVAILABLE)	$_____	62 67
		78 0 4 3 80

ITEM OR SERVICE (Continued)	CHARGE	(Dup 1-6)
J. OTHER SERVICES	$_____	7 — — — — — 12
K. MISCELLANEOUS	$_____	13 — — — — — 18
L. PROFESSIONAL FEES		
L.1. ANESTHESIOLOGY	$_____	19 — — — — 23
L.2. CARDIOLOGY	$_____	— — — — —
L.3. SURGERY	$_____	29 — — — — 33
L.4. RADIOLOGY	$_____	— — — — —
L.5. PULMONARY PHYSICIAN	$_____	39 — — — — 43
L.6. OCCUPATIONAL THERAPIST	$_____	— — — — —
L.7. OTHER (SPECIFY) _____	$_____	49 — — — — 53
L.8. OTHER (SPECIFY) _____	$_____	— — — — —
L.9. OTHER (SPECIFY) _____	$_____	59 — — — — 63
L.10. OTHER (SPECIFY) _____	$_____	— — — — —
L.11. TOTAL PROFESSIONAL FEES (IF AVAILABLE)	$_____	69 — — — — — 74
		78 **0 4 4** 80
M. ROOM AND BOARD		(Dup 1-6)
M.1. ICU (SURGICAL)	$_____	— — — — — 11
M.2. ICU (OTHER)	$_____	— — — — —
M.3. CCU	$_____	17 — — — — 21
M.4. GENERAL WARD (PRIVATE)	$_____	— — — — —
M.5. GENERAL WARD (SEMI-PRIVATE)	$_____	27 — — — — 31
M.6. GENERAL WARD (OTHER)	$_____	— — — — —
M.7. OTHER (SPECIFY) _____	$_____	37 — — — — 41
M.8. TOTAL ROOM AND BOARD (IF AVAILABLE)	$_____	42 — — — — — 47

ITEM OR SERVICE (Continued)	CHARGE
N. HISTOCOMPATIBILITY TESTING (DONOR ONLY)	$_____
O. TRANSPORTATION CHARGE	$_____
GRAND TOTAL	$_____

48 — — — — — — 53

— — — — — —

60 — — — — — — 65

0 4 5
78 80

86. We are particularly interested in how the charges for organ procurement were handled. *(NOTE: Source of PAYMENT may be the same as those for the TRANSPLANTATION period.)*

a) Please indicate **all** sources of payment

(CIRCLE YES OR NO FOR EACH PAYMENT SOURCE)

(Dup 1-6)

		YES	NO	
86. 1	SELF-PAY	01	02	— — 8
86. 2	OTHER FAMILY MEMBERS	01	02	— —
86. 3	MEDICARE	01	02	— — 11 12
86. 4	MEDICAID	01	02	— —
86. 5	CHAMPUS	01	02	— — 15 16
86. 6	OTHER GOVERNMENT PROGRAM	01	02	— —
86. 7	BLUE CROSS/BLUE SHIELD	01	02	— — 19 20
86. 8	OTHER PRIVATE OR COMMERCIAL INSURANCE	01	02	— —
86. 9	RESEARCH GRANT FUNDS (e.g.NIH)	01	02	— — 23 24
86.10	SPECIAL PATIENT FUND	01	02	— —
86.11	OTHER ANONYMOUS CONTRIBUTIONS	01	02	— —
86.12	OTHER (SPECIFY) _____	01	02	— — 29 30

b) Which of the above was the **principal** source of payment?

_____

PRINCIPAL SOURCE OF PAYMENT — — 31 32

87. What is the approximate dollar amount breakdown of charges paid by each source for the donor heart? *(Please place a check in the box below if it is impossible to break out separately the charges for the donor heart from the overall transplant bill.)*

☐ IMPOSSIBLE TO BREAK OUT DONOR HEART CHARGES ACCORDING TO SOURCE OF PAYMENT

		RECORD DOLLARS	
87.1	SELF-PAY	$_____	33 — 38
87.2	OTHER FAMILY MEMBERS	$_____	— — — — — —
87.3	MEDICARE	$_____	45 — 50
			78 **0 4 6** 80
			(Dup 1-6)
87.4	MEDICAID	$_____	7 — 12
87.5	CHAMPUS	$_____	— — — — — —
87.6	OTHER U.S. GOVERNMENT PROGRAM	$_____	19 — 24
87.7	BLUE CROSS/BLUE SHIELD	$_____	— — — — — —
87.8	PRIVATE OR COMMERCIAL INSURANCE	$_____	31 — 36
87.9	RESEARCH GRANT FUNDS (e.g., NIH)	$_____	— — — — — —
87.10	SPECIAL PATIENT FUND	$_____	43 — 48
87.11	OTHER ANONYMOUS CONTRIBUTIONS	$_____	— — — — — —
87.12	OTHER (SPECIFY)_____	$_____	55 — 60

MORTALITY DATA

88. Is this patient currently living or deceased?

(CIRCLE ONE)

LIVING 01

DECEASED ..... 02 **(SKIP TO Q.91)**

61 — 62

78 **0 4 7** 80

FOR LIVING HEART TRANSPLANT RECIPIENTS ONLY

FUNCTIONAL STATUS DATA

89. What is this patient's current functional classification according to the New York Heart Classification?

(CIRCLE ONE)

CLASS I. Patients with cardiac disease but without resulting limitations of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain 01

(Dup 1-6)

CLASS II. Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain 02

7 8

CLASS III. Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary physical activity causes fatigue, palpitation, dyspnea, or anginal pain 03

CLASS IV. Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of cardiac insufficiency or of the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased 04

90. Please check the statement below which best describes this patient's current condition.

(CIRCLE ONE)

NORMAL; NO COMPLAINTS; NO EVIDENCE OF DISEASE 01

ABLE TO CARRY ON NORMAL ACTIVITY: MINOR SIGNS AND SYMPTOMS OF DISEASE 02

NORMAL ACTIVITY WITH EFFORT; SOME SIGNS AND SYMPTOMS OF DISEASE 03

CARE FOR SELF; UNABLE TO CARRY ON NORMAL ACTIVITY OR DO ACTIVE WORK 04

REQUIRES OCCASIONAL ASSISTANCE BUT IS ABLE TO CARE FOR MOST OF OWN NEEDS 05

REQUIRES CONSIDERABLE ASSISTANCE AND FREQUENT MEDICAL CARE 06

DISABLED; REQUIRES SPECIAL CARE AND ASSISTANCE 07

SEVERELY DISABLED; HOSPITALIZATION IS INDICATED ALTHOUGH DEATH NOT IMMINENT 08

VERY SICK; HOSPITALIZATION NECESSARY..... 09

MORIBUND; FATAL PROCESSES PROGRESSING RAPIDLY 10

9 10

END OF QUESTIONNAIRE -- DO NOT CONTINUE BEYOND THIS PAGE

FOR DECEASED HEART TRANSPLANT RECIPIENTS ONLY

MORTALITY DATA

91. On what date did this patient expire?

_____ / ____ / _____
MONTH DAY YEAR

11 — — — — — —

92. Where did this patient expire?

(CIRCLE ONE)

IN YOUR HOSPITAL 01
IN ANOTHER HOSPITAL 02
OUT OF HOSPITAL BUT IN YOUR CITY 03
OUT OF HOSPITAL--AT PATIENT'S HOME 04
OUT OF HOSPITAL BUT NOT AT HOME 05
UNKNOWN 06

17 — 18

93. On what date did your program last have contact with this patient?

_____ / ____ / _____
MONTH DAY YEAR

19 — — — — — 24

94. To your knowledge, what was the underlying (primary) cause of death of this patient?

_____
UNDERLYING CAUSE OF DEATH

25 — — — 28

95. To your knowledge, what were the contributory causes of death for this patient? *(PLEASE LIST UP TO FOUR)*

95.1. _____ 29 — — — 32
95.2. _____ — — — —
95.3. _____ — — — —
95.4. _____ 41 — — — 44

96. Did this patient live at least one year and have at least one **ANNUAL** examination?

(CIRCLE ONE)

YES ..... 01 **(CONTINUE)**
NO ..... 02 **(STOP)**

45 — 46

97. What was the date of this patient's most recent **ANNUAL** examination?

_____/____/_____
MONTH DAY YEAR

47 — — — — — — 52

98. What was the patient's functional classification according to the New York Heart Classification at the time of their most recent **ANNUAL** examination?

(CIRCLE ONE)

CLASS I. Patients with cardiac disease but without resulting limitations of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain 01

CLASS II. Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain 02

53 54

CLASS III. Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary physical activity causes fatigue, palpitation, dyspnea, or anginal pain 03

CLASS IV. Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of cardiac insufficiency or of the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased 04

99. Please check the statement below which best describes this patient at the time of their most recent **ANNUAL** examination?

(CIRCLE ONE)

NORMAL; NO COMPLAINTS; NO EVIDENCE OF DISEASE 01

ABLE TO CARRY ON NORMAL ACTIVITY: MINOR SIGNS AND SYMPTOMS OF DISEASE 02

NORMAL ACTIVITY WITH EFFORT; SOME SIGNS AND SYMPTOMS OF DISEASE 03

CARE FOR SELF; UNABLE TO CARRY ON NORMAL ACTIVITY OR DO ACTIVE WORK 04

REQUIRES OCCASIONAL ASSISTANCE BUT IS ABLE TO CARE FOR MOST OF OWN NEEDS 05

REQUIRES CONSIDERABLE ASSISTANCE AND FREQUENT MEDICAL CARE 06

DISABLED; REQUIRES SPECIAL CARE AND ASSISTANCE 07

SEVERELY DISABLED; HOSPITALIZATION IS INDICATED ALTHOUGH DEATH NOT IMMINENT 08

VERY SICK; HOSPITALIZATION NECESSARY 09

MORIBUND; FATAL PROCESSES PROGRESSING RAPIDLY 10

55 56

78 0 4 8 80

APPENDIX 6-B

NONRECIPIENT MEDICAL AND HOSPITAL RECORDS DATA ABSTRACTION FORM

NONRECIPIENT

MEDICAL AND HOSPITAL RECORDS DATA ABSTRACTION FORM

NATIONAL HEART TRANSPLANTATION STUDY*

Health and Population Study Center
Battelle Human Affairs Research Centers
4000 N.E. 41st Street
Seattle, Washington 98105
Telephone (206) 525-3130

* [illegible] by the Office of Research and Demonstrations, Health Care Financing Administration, [illegible]

NOTE: THIS IS A TEARSHEET

THIS PAGE IS TO BE REMOVED BEFORE THIS FORM IS RETURNED TO THE BATTELLE HUMAN AFFAIRS RESEARCH CENTERS

What is this patient's name, complete address, and telephone number?

Name _____
First Middle Last

Street Address _____
City State Zip Code

Telephone (_____) _____
Area Code

What is this patient's hospital identification number; that is, the number assigned to the patient during the time he/she was being evaluated as a heart transplant candidate?

_____
HOSPITAL IDENTIFICATION NUMBER

CHECK THE BOX PROVIDED BELOW IF THE PATIENT WAS NOT ASSIGNED A NUMBER.

☐ *THIS PATIENT WAS NOT ASSIGNED A HOSPITAL I.D. NUMBER*

INTRODUCTION

This data form should be completed for **ALL** patients who have been **referred** to your program for a heart transplant since January 1, 1978 through June 30, 1983, but have not received a transplant. This includes those patients your program has identified as potential heart transplant recipients who are still awaiting the identification of a suitable donor. Please note that a different data form should be completed for all patients who have received a transplant (regardless of whether the patient is currently living or deceased). Only patients for whom a telephone inquiry was made, without followup, should be excluded from the study.

We recognize that a patient may be referred for an evaluation in several different ways and that the evaluation itself may vary in extent. Some patients may undergo an extensive and comprehensive evaluation (a small fraction of the total number) while others, although referred as possible candidates for a heart transplant, may be turned down after the review of laboratory tests, studies, and psychosocial evaluations submitted by their referring cardiologist. In short, some patients are evaluated for a heart transplant who have never physically been to your institution for evaluation. Guidelines for deciding which patients this form should be completed for are provided below.

PATIENTS FOR WHOM *NO* FORM SHOULD BE COMPLETED:

- any patient for whom a simple telephone inquiry was made by a referring cardiologist, but no laboratory test data, study results, or psychosocial evaluations were submitted for consideration

PATIENTS FOR WHOM *THIS* FORM SHOULD BE COMPLETED:

- any patient for whom test results, studies, and psychosocial evaluations were submitted by a referring cardiologist
- any patient who came to your institution (e.g., drop-ins) for consideration as a possible transplant candidate and for whom tests, studies, and a psychosocial evaluation were completed
- any patient turned down as a suitable candidate for a heart transplant
- any patient accepted as a heart transplant candidate but died before receiving a heart transplant
- any patient accepted as a heart transplant candidate but was later deselected due to improved health status
- any patient accepted as a heart transplant candidate but is still awaiting the identification of a suitable donor

CODES FOR MISSING OR UNAVAILABLE DATA

In any research study, such as the National Heart Transplantation Study, there will always be data which are "missing." The important point, however, is that there are several types of missing data. To make certain that this form is filled out properly and at the same time to provide a clear indication of why certain questions are unanswered, we have adopted a special set of missing data codes as well as specifying conventions for indicating why the data are missing. In completing this form, the following abbreviations should be used to signify missing data:

ABBREVIATION	DEFINITION
DK	**DON'T KNOW** - no data are available to answer the questions as stated in the data collection instrument.
MISSING	**MISSING** - data that were likely to have been available at some point in time, but a review of hospital and medical records does not provide the required data should be recorded as "missing."
NP	**NOT PERFORMED** - if a given test was not performed and, thus, the test results are unavailable, an "NP" should be recorded on the form.

DEFINITIONS

To assist with the completion of this form, the following definitions are provided:

PRE-EVALUATION PERIOD - For patients who have their evaluation secondary to a hospitalization not initially intended for heart transplant evaluation, the pre-evaluation period is the time period between the date of their initial hospitalization (i.e., admission date) and the date on which additional transplant-related evaluation tests were done. Patients who are hospitalized specifically for purposes of evaluation will not have a pre-evaluation period; however, patients who were already hospitalized before their evaluation will have a pre-evaluation period.

EVALUATION PERIOD - The evaluation period is the period between the date on which heart transplant evaluation tests were performed on the patient and the date the patient was accepted or rejected as a heart transplant candidate.

CANDIDACY PERIOD - The candidacy period is the period between the date the patient was accepted as a heart transplant candidate and the date of the day before the patient received his/her heart transplant. If the patient died prior to receiving a heart transplant, the candidacy period is the period between the date the patient was accepted as a heart transplant candidate and the date of their death.

TRANSPLANTATION PERIOD - The transplantation period is the period between the date the patient received his/her transplant and the date of his/her initial discharge from the hospital following transplant surgery, or the date the patient expired if this occurred prior to initial discharge.

POST-TRANSPLANT PERIOD - The post-transplant period is the period between the date of the patient's initial discharge from the hospital and June 30, 1983 or the date that he/she died.

THESE QUESTIONS ARE TO BE ANSWERED FOR ALL PATIENTS WHO WERE EVER EVALUATED AS POTENTIAL HEART TRANSPLANT RECIPIENTS

PATIENT STUDY I.D. NUMBER _____ 1 — — — — — — 6

DATE THIS FORM WAS COMPLETED _____ 7 — — — — — — 12

REFERRAL DATA

1. Was this patient referred to your program by an in-house physician, a physician outside your hospital, or was the patient self-referred (e.g., a drop-in)?

(CIRCLE ONE)

IN-HOUSE PHYSICIAN 01

OUTSIDE PHYSICIAN 02

SELF-REFERRED ..... 03 **(SKIP TO Q.4)**

13 — 14

2. If this patient was referred to your program by another physician, please provide the complete name, address, telephone number, and medical specialty of the referring physician.

_____
Physician's Full Name

_____
Institutional Affiliation

15 — 16

_____
Street Address

17 — — — — — 21

_____
City State Zip Code

( )
_____
Area Code Telephone Number

3. _____
Medical Specialty of Referring Physician

22 — 23

4. On what date was this patient initially referred to your heart transplant program for evaluation? (*PLEASE RECORD MONTH, DAY, AND YEAR.*)

_____ / / _____
MONTH DAY YEAR

24 — — — — — 29

5. To your knowledge, was this patient previously evaluated by another heart transplant program?

(CIRCLE ONE)

YES 01

NO ..... 02 **(SKIP TO Q.8)**

DON'T KNOW ..... -2 **(SKIP TO Q.8)**

30 31

6. How many times has this patient been evaluated by a heart transplant program for purposes of receiving a heart transplant?

_____

NUMBER OF TIMES PATIENT HAS BEEN EVALUATED

32 33

7. At what other heart transplant programs was this patient evaluated before coming to your program? *(LIST ALL PROGRAMS BY NAME ONLY.)*

_____ 34 35

_____

_____ 38 39

_____

_____ 42 43

DEMOGRAPHIC AND PATIENT SELECTION DATA

8. What is this patient's birthdate?

_____ 44 49

MONTH DAY YEAR

9. Is this patient a male or female? *(CIRCLE ONE)*

MALE 01

FEMALE 02

50 51

0. What is this patient's race?

(CIRCLE ONE)

BLACK (NEGRO) 01

CHICANO (MEXICAN-AMERICAN) 02

NATIVE AMERICAN (AMERICAN INDIAN, ESKIMO, ALEUT) 03

WHITE (CAUCASIAN) 04

ORIENTAL (ASIAN AMERICAN OR PACIFIC ISLANDER) 05

OTHER 06

DON'T KNOW ..... -2

1. At the time of this patient's evaluation, what was his/her marital status?

(CIRCLE ONE)

SINGLE, NEVER MARRIED 01

MARRIED, SPOUSE PRESENT 02

MARRIED, SPOUSE ABSENT 03

SEPARATED 04

DIVORCED 05

WIDOWED 06

DON'T KNOW ..... -2

2. How many children were in the family?

NUMBER OF CHILDREN _____

52 53

54 55

78 1 0 1 80

(Dup 1-6)

7 8

13. What were the ages of the children?

13.1 CHILD 1	_____	13.6 CHILD 6	_____
13.2 CHILD 2	_____	13.7 CHILD 7	_____
13.3 CHILD 3	_____	13.8 CHILD 8	_____
13.4 CHILD 4	_____	13.9 CHILD 9	_____
13.5 CHILD 5	_____	13.10 CHILD 10	_____

14. What was this patient's employment status at the time of evaluation?

(CIRCLE ONE)

EMPLOYED FULL-TIME 01

EMPLOYED PART-TIME 02

EMPLOYED BUT TEMPORARILY LAID OFF 03

UNEMPLOYED, LOOKING FOR WORK 04

UNEMPLOYED, NOT LOOKING FOR WORK 05

UNABLE TO WORK
BECAUSE OF HEALTH (DISABLED) 06

HOMEMAKER 07

STUDENT (FULL-TIME) 08

RETIRED 09

OTHER (SPECIFY) _____ 10

DON'T KNOW ..... -2

15. Historically, which of the following would best describe this patient's employment status?

(CIRCLE ONE)

EMPLOYED FULL-TIME	01
EMPLOYED PART-TIME	02
EMPLOYED BUT TEMPORARILY LAID OFF	03
UNEMPLOYED, LOOKING FOR WORK	04
UNEMPLOYED, NOT LOOKING FOR WORK	05
UNABLE TO WORK BECAUSE OF HEALTH (DISABLED)	06
HOMEMAKER	07
STUDENT (FULL-TIME)	08
RETIRED	09
OTHER (SPECIFY) _____	10
DON'T KNOW	-2

31 32

16. Is this patient a U.S. citizen?

(CIRCLE ONE)

YES	01 **(SKIP TO Q.18)**
NO	02

33 34

17. What is this patient's country of residence?

_____

35 — 37

18. What was this patient's primary preoperative diagnosis at the time of his/her evaluation by your program?

(CIRCLE ONE)

CORONARY ARTERY DISEASE 01

IDIOPATHIC CARDIOMYOPATHY 02

VALVE DISEASE WITH CARDIOMYOPATHY 03

RHEUMATIC VALVULAR DISEASE 04

POSTTRAUMATIC ANEURYSM 05

CONGENITAL HEART DISEASE 06

CARDIAC TUMOR 07

OTHER (SPECIFY) _____ 08

38 39

1 0 2
28 30

19. What contraindications for heart transplantation, if any, did this patient exhibit? *(RECORD ALL CONTRAINDICATIONS. FOR ANY CONTRAINDICATIONS NOT LISTED, SPECIFY ON LINES PROVIDED.)*

(Dup 1-6)

		(CIRCLE YES OR NO FOR EACH ITEM) YES	NO	
19.1	SEVERE PULMONARY HYPERTENSION	01	02	8
19.2	IRREVERSIBLE AND SEVERE HEPATIC DYSFUNCTION	01	02	
19.3	IRREVERSIBLE AND SEVERE RENAL DYSFUNCTION	01	02	11 12
19.4	ACTIVE SYSTEMIC INFECTION	01	02	
19.5	OTHER SYSTEMIC DISEASE LIKELY TO LIMIT OR PRECLUDE SURVIVAL AND REHABILITATION AFTER TRANSPLANTATION.....	01	02	15 16
19.6	PSYCHIATRIC ILLNESS OR SEVERE BEHAVIORAL DISORDER	01	02	
19.7	PHYSICAL HANDICAP	01	02	19 20
19.8	RECENT AND UNRESOLVED PULMONARY INFARCTION	01	02	
19.9	INSULIN-REQUIRING DIABETES MELLITUS	01	02	23 24

	YES	NO	
19.10 SYMPTOMATIC OR DOCUMENTED SEVERE ASYMPTOMATIC PERIPHERAL OR CEREBROVASCULAR DISEASE	01	02	25 26
19.11 ACTIVE PEPTIC ULCER DISEASE	01	02	27 28
19.12 ABSENCE OF ADEQUATE EXTERNAL PSYCHOSOCIAL SUPPORT	01	02	29 30
19.13 ADVANCING AGE (UNABLE TO WITHSTAND SURGERY OR POSTOPERATIVE COMPLICATIONS)	01	02	31 32
19.14 PULMONARY VASCULAR RESISTANCE **GREATER** THAN EIGHT WOOD UNITS	01	02	33 34
19.15 DRUG OR ALCOHOL ADDICTION	01	02	35 36
19.16 GOOD PROGNOSIS DESPITE CARDIAC DISEASE (BETTER THAN 10-25 PERCENT LIKELIHOOD OF SURVIVING FOR 6 MONTHS)	01	02	37 38
19.17 OTHER (SPECIFY) _____	01	02	39 40
19.18 OTHER (SPECIFY) _____	01	02	41 42
19.19 OTHER (SPECIFY) _____	01	02	43 44
19.20 OTHER (SPECIFY) _____	01	02	45 46

FUNCTIONAL STATUS DATA

20. At the time of evaluation, what was this patient's functional classification according to the New York Heart Classification?

(CIRCLE ONE)

CLASS I. Patients with cardiac disease but without resulting limitations of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain 01

CLASS II. Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain 02

CLASS III. Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary physical activity causes fatigue, palpitation, dyspnea, or anginal pain 03

CLASS IV. Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of cardiac insufficiency or of the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased 04

47 48

21. Please circle the number of the statement below which best describes this patient's functional status at the time of their evaluation.

(CIRCLE ONE)

NORMAL; NO COMPLAINTS; NO EVIDENCE OF DISEASE	01
ABLE TO CARRY ON NORMAL ACTIVITY; MINOR SIGNS AND SYMPTOMS OF DISEASE	02
NORMAL ACTIVITY WITH EFFORT; SOME SIGNS AND SYMPTOMS OF DISEASE	03
CARE FOR SELF; UNABLE TO CARRY ON NORMAL ACTIVITY OR DO ACTIVE WORK	04
REQUIRES OCCASIONAL ASSISTANCE BUT IS ABLE TO CARE FOR MOST OF OWN NEEDS	05
REQUIRES CONSIDERABLE ASSISTANCE AND FREQUENT MEDICAL CARE	06
DISABLED; REQUIRES SPECIAL CARE AND ASSISTANCE	07
SEVERELY DISABLED; HOSPITALIZATION IS INDICATED ALTHOUGH DEATH NOT IMMINENT	08
VERY SICK; HOSPITALIZATION NECESSARY	09
MORIBUND; FATAL PROCESSES PROGRESSING RAPIDLY	10
STATUS UNKNOWN	-2

49 50

FINANCIAL AND INSURANCE STATUS DATA

22. What was this patient's approximate yearly income at the time of evaluation?

$_____
YEARLY INCOME

51 57

23. Was this patient eligible for Medicare Part A, Medicare Part B, or both Medicare Part A and Part B benefits or neither at the time of evaluation?

(CIRCLE ONE)

MEDICARE PART A	01
MEDICARE PART B	02
BOTH MEDICARE PART A AND PART B	03
NOT ELIGIBLE FOR MEDICARE PART A OR B	04
DON'T KNOW	-2

58 59

24. Was this patient eligible for Medicaid benefits at the time of evaluation?

(CIRCLE ONE)

YES	01
NO	02
DON'T KNOW	-2

60 61

25. Did this patient have health insurance through a private insurer?

(CIRCLE ONE)

YES	01
NO	02 **(SKIP TO Q.29)**

62 63

26. What was the name of the insurance company?

_____

NAME OF INSURER

64 67

1 0 3

78 80

27. Was the private insurer consulted concerning payment for heart transplantation?

(Dup 1-6)

(CIRCLE ONE)

YES 01

NO ..... 02 **(SKIP TO Q.29)**

DON'T KNOW ..... -2 **(SKIP TO Q.29)**

7 8

28. To your knowledge, did the patient's private insurer view heart transplantation as experimental or therapeutic?

(CIRCLE ONE)

EXPERIMENTAL 01

THERAPEUTIC 02

DON'T KNOW, NO DETERMINATION MADE . -2

9 10

29. Was this patient a veteran?

(CIRCLE ONE)

YES 01

NO ..... 02 **(SKIP TO Q.31)**

DON'T KNOW ..... -2 **(SKIP TO Q.31)**

11 12

30. Was he/she eligible for benefits under the CHAMPUS program?

(CIRCLE ONE)

YES 01

NO 02

DON'T KNOW ..... -2

13 14

EVALUATION PERIOD FINANCIAL DATA

31. Did this patient undergo a complete medical examination at your institution or were the results of various laboratory and diagnostic tests submitted by the referring physician?

(CIRCLE ONE)

PATIENT UNDERWENT COMPLETE EVALUATION 01

RESULTS OF TESTS WERE SUBMITTED BUT PATIENT NEVER CAME TO OUR INSTITUTION FOR COMPLETE EVALUATION ..... 02 **(SKIP TO Q.45)**

15 16

32. Was this patient already hospitalized at your institution at the time of their evaluation or was he/she admitted specifically for purposes of evaluation?

(CIRCLE ONE)

HOSPITALIZED BEFORE EVALUATION 01

17 18

HOSPITALIZED SPECIFICALLY FOR EVALUATION ..... 02 **(SKIP TO Q.34)**

33. On what date was the patient initially hospitalized?

_____

MONTH DAY YEAR

19 — — — — — 24

34. On what date did this patient's evaluation begin?

_____

MONTH DAY YEAR

25 — — — — — 30

35. How many days, if any, was this patient hospitalized at your institution in the ICU, CCU, and general ward during the **PRE-EVALUATION** period? Recall the **PRE-EVALUATION** period is the period between the dates specified in Q.33 and Q.34, above. *(IF THE PATIENT DID NOT HAVE A PRE-EVALUATION PERIOD, ZEROS SHOULD BE ENTERED ON ALL LINES.)*

	ROOM	NUMBER OF DAYS	
35.1	ICU (SURGICAL)	_____	31 — — 33
35.2	ICU (OTHER)	_____	34 — — 36
35.3	CCU	_____	37 — — 39
35.4	GENERAL WARD (PRIVATE)	_____	40 — — 42
35.5	GENERAL WARD (SEMI-PRIVATE)	_____	43 — — 45
35.6	GENERAL WARD (OTHER)	_____	46 — — 48
35.7	OTHER (SPECIFY) _____	_____	49 — — 51

36. On what date did this patient's **EVALUATION** formally end?

_____
MONTH DAY YEAR

52 — — — — — 57

37. On the basis of the **EVALUATION**, was this patient accepted or rejected as a heart transplant candidate?

(CIRCLE ONE)

ACCEPTED 01

REJECTED 02

58 — 59

38. On what date was he/she accepted or rejected as a heart transplant candidate?

_____
MONTH DAY YEAR

60 — — — — — 65

39. Is the date the evaluation began (see Question 34, above) between January 1, 1978 and June 30, 1983?

(CIRCLE ONE)

YES 01

NO ..... 02 **(SKIP TO Q. 45)**

66 67

1 0 4

78 80

40. Charges for a patient's **EVALUATION** can be broken down into several categories including laboratory tests, diagnostic tests, drugs, medical and surgical supplies, room and board, and professional fees. Please provide a complete breakdown of charges for the **EVALUATION** period according to these major categories. Any items that do not fit these categories should be totaled and placed in the "other" category. Recall that the **EVALUATION** period is the period between the date on which the patient's **EVALUATION** began (see Q. 34, above) and the date on which the patient was accepted or rejected as a heart transplant candidate (see Q. 38, above).

ITEM OR SERVICE	CHARGE
A. MEDICAL, SURGICAL, AND CENTRAL SUPPLIES	
A.1. MEDICAL SUPPLIES	$_____
A.2. SURGICAL SUPPLIES	$_____
A.3. CENTRAL SUPPLIES	$_____
A.4. OTHER SUPPLIES	$_____
A.5. TOTAL SUPPLIES (IF AVAILABLE)	$_____
B. OPERATING ROOM AND ANESTHESIA	
B.1. OPERATING ROOM	$_____
B.2. ANESTHESIA (EXCLUDING PROFESSIONAL TIME)	$_____
B.3. OTHER (SPECIFY) _____	$_____
B.4. TOTAL OPERATING ROOM AND ANESTHESIA (IF AVAILABLE)	$_____

(Dup 1-6)

11

17 21

27 32

38 42

48 53

1 0 5

78 80

ITEM OR SERVICE (Continued)	CHARGE
C. PHARMACY	
C.1. DRUGS, IN-HOSPITAL	$_____
C.2. DRUGS, TAKE-HOME OR DISCHARGE	$_____
C.3. I.V. SOLUTIONS	$_____
C.4. ALL OTHER DRUGS	$_____
C.5. TOTAL PHARMACY (IF AVAILABLE)	$_____
D. THERAPY	
D.1. RESPIRATORY INHALATION THERAPY	$_____
D.2. VOCATIONAL/OCCUPATIONAL THERAPY	$_____
D.3. PHYSICAL THERAPY/PHYSICAL MEDICINE	$_____
D.4. OTHER THERAPY	$_____
D.5. TOTAL THERAPY (IF AVAILABLE)	$_____
E. APPLIANCES	$_____

(Dup 1-6)

1 0 6

ITEM OR SERVICE (Continued)	CHARGE
F. DIAGNOSTIC TESTS	
F.1. EKG	$_____
F.2. CARDIAC MONITORING/CARDIAC CATH LAB	$_____
F.3. RADIOLOGY (X-RAY)	$_____
F.4. RADIATION MEDICINE	$_____
F.5. NUCLEAR MEDICINE	$_____
F.6. INFECTIOUS DISEASE	$_____
F.7. SURGICAL PATHOLOGY	$_____
F.8. OTHER DIAGNOSTIC TESTS	$_____
F.9. TOTAL DIAGNOSTIC TESTS (IF AVAILABLE)	$_____
G. BLOOD ADMINISTRATION	
G.1. BLOOD TRANSFUSION	$_____
G.2. BLOOD BANK	$_____
G.3. COAGULATION LABORATORY	$_____
G.4. BLOOD PROCESSING	$_____
G.5. BLOOD PLASMA (PROC)	$_____
G.6. BLOOD ADMINISTRATION	$_____
G.7. BLOOD LAB	$_____
G.8. OTHER (SPECIFY) _____	$_____
G.9. TOTAL BLOOD AND ADMINISTRATION (IF AVAILABLE)	$_____
H. OXYGEN AND GAS MIXTURES	$_____

(Dup 1-6)

(Dup 1-6)

1 0 7

1 0 8

ITEM OR SERVICE (Continued)	CHARGE	
I. LABORATORY TESTS		(Dup 1-6)
I.1. HEMATOLOGY	$_____	7 — — — — 11
I.2. CHEMISTRY	$_____	— — — — —
I.3. IMMUNOLOGY/IMMUNOPATHOLOGY	$_____	17 — — — — 21
I.4. PULMONARY PHYSIOLOGY	$_____	— — — — —
I.5. VIROLOGY	$_____	27 — — — — 31
I.6. MICROBIOLOGY	$_____	— — — — —
I.7. DRUG ASSAY	$_____	37 — — — — 41
I.8. CLINICAL LABORATORY TESTS (IF GIVEN)	$_____	— — — — —
I.9. PATHOLOGY LABORATORY TESTS (IF GIVEN)	$_____	47 — — — — 51
I.10. ICU LABORATORY TESTS	$_____	— — — — —
I.11. OTHER LABORATORY TESTS	$_____	57 — — — — 61
I.12. TOTAL LABORATORY TESTS (IF AVAILABLE)		62 — — — — 67
		1 0 9 (78 — 80)
		(Dup 1-6)
J. OTHER SERVICES	$_____	— — — — — 12
K. MISCELLANEOUS	$_____	13 — — — — 18

ITEM OR SERVICE (Continued)	CHARGE
L. PROFESSIONAL FEES	
L.1. ANESTHESIOLOGY	$_____
L.2. CARDIOLOGY	$_____
L.3. SURGERY	$_____
L.4. RADIOLOGY	$_____
L.5. PULMONARY PHYSICIAN	$_____
L.6. OCCUPATIONAL THERAPIST	$_____
L.7. OTHER (SPECIFY) _____	$_____
L.8. OTHER (SPECIFY) _____	$_____
L.9. OTHER (SPECIFY) _____	$_____
L.10. OTHER (SPECIFY) _____	$_____
L.11. TOTAL PROFESSIONAL FEES (IF AVAILABLE)	$_____
M. ROOM AND BOARD	
M.1. ICU (SURGICAL)	$_____
M.2. ICU (OTHER)	$_____
M.3. CCU	$_____
M.4. GENERAL WARD (PRIVATE)	$_____
M.5. GENERAL WARD (SEMI-PRIVATE)	$_____
M.6. GENERAL WARD (OTHER)	$_____
M.7. OTHER (SPECIFY) _____	$_____
M.8. TOTAL ROOM AND BOARD (IF AVAILABLE)	$_____
GRAND TOTAL	$_____

41. How many days did this patient spend in the ICU, CCU, and general ward during the **EVALUATION** period?

	ROOM	NUMBER OF DAYS	(Dup 1-6)
41.1	ICU (SURGICAL)	_____	___ ___ ___ (7–9)
41.2	ICU (OTHER)	_____	___ ___ ___
41.3	CCU	_____	___ ___ ___ (13–15)
41.4	GENERAL WARD (PRIVATE)	_____	___ ___ ___
41.5	GENERAL WARD (SEMI-PRIVATE)	_____	___ ___ ___ (19–21)
41.6	GENERAL WARD (OTHER)	_____	___ ___ ___
41.7	OTHER (SPECIFY) _____ ...	_____	___ ___ ___ (25–27)

42. To whom were charges made for the care of this patient during the **EVALUATION** period?

a) Please indicate **all** sources of payment.

(CIRCLE YES OR NO FOR EACH PAYMENT SOURCE)

		YES	NO	
42.1	SELF-PAY	01	02	28 29
42.2	OTHER FAMILY MEMBERS	01	02	— —
42.3	MEDICARE	01	02	32 33
42.4	MEDICAID	01	02	— —
42.5	CHAMPUS	01	02	36 37
42.6	OTHER GOVERNMENT PROGRAM	01	02	— —
42.7	BLUE CROSS/BLUE SHIELD	01	02	— —
42.8	OTHER PRIVATE OR COMMERCIAL INSURANCE	01	02	42 43
42.9	RESEARCH GRANT FUNDS (e.g., NIH)	01	02	— —
42.10	SPECIAL PATIENT FUND	01	02	46 47
42.11	OTHER ANONYMOUS CONTRIBUTIONS	01	02	— —
42.12	OTHER (SPECIFY) _____	01	02	50 51

b) Which of the above was the **principal** source of payment?

_____

PRINCIPAL SOURCE OF PAYMENT

52 53

43. What is the approximate dollar amount of charges paid by each source for the **EVALUATION** period?

		RECORD DOLLARS	
43.1	SELF-PAY	$_____	54 — 59
43.2	OTHER FAMILY MEMBERS	$_____	— — — — — —
43.3	MEDICARE	$_____	66 — 71
			78 **1** **1** **2** 80
			(Dup 1-6)
43.4	MEDICAID	$_____	7 — 12
43.5	CHAMPUS	$_____	— — — — — —
43.6	OTHER GOVERNMENT PROGRAM	$_____	19 — 24
43.7	BLUE CROSS/BLUE SHIELD	$_____	— — — — — —
43.8	PRIVATE OR COMMERCIAL INSURANCE	$_____	31 — 36
43.9	RESEARCH GRANT FUNDS (e.g., NIH)	$_____	— — — — — —
43.10	SPECIAL PATIENT FUND	$_____	43 — 48
43.11	OTHER ANONYMOUS CONTRIBUTIONS	$_____	— — — — — —
43.12	OTHER (SPECIFY) _____	$_____	55 — 60

44. How much, if any, of this patient's hospital bill for **EVALUATION** was eventually written off by the hospital as bad debt?

BAD DEBT $_____

☐ CHECK IF UNKNOWN

61 — 66

78 **1** **1** **3** 80

45. Based on the results of this patient's evaluation, which of the following best describes what happened to this patient? Was he/she turned down as a suitable candidate for a heart transplant, accepted as a heart transplant candidate but died before receiving a heart transplant, or accepted as a heart transplant candidate but was deselected or is still awaiting the identification of a suitable donor?

(CIRCLE ONE)

TURNED DOWN AS A SUITABLE CANDIDATE FOR A HEART TRANSPLANT	01	**(GO TO Q.46)**
ACCEPTED AS A HEART TRANSPLANT CANDIDATE BUT DIED BEFORE RECEIVING ONE	02	**(SKIP TO Q.56)**
ACCEPTED AS A HEART TRANSPLANT CANDIDATE BUT WAS DESELECTED AS A HEART TRANSPLANT CANDIDATE OR IS STILL AWAITING THE IDENTIFICATION OF A SUITABLE DONOR	03	**(SKIP TO Q.68)**
ACCEPTED AS A HEART TRANSPLANT CANDIDATE BUT WAS NOT TRANSPLANTED BY PATIENT'S CHOICE	04	**(STOP. END OF QUESTIONNAIRE)**

(Dup 1-6)

7 8

THESE QUESTIONS ARE ONLY FOR THOSE PATIENTS WHO WERE TURNED DOWN AS SUITABLE CANDIDATES FOR A HEART TRANSPLANT

46. On what basis was it concluded that this patient should not receive a heart transplant? Please indicate the major findings of the evaluation as they pertain to this case.

(CIRCLE YES OR NO FOR EACH ITEM)

		YES	NO	
46.1	NYHC OTHER THAN CLASS IV	01	02	9 10
46.2	SEVERE PULMONARY HYPERTENSION	01	02	11 12
46.3	IRREVERSIBLE AND SEVERE RENAL DYSFUNCTION	01	02	13 14
46.4	ACTIVE SYSTEMIC INFECTION	01	02	15 16
46.5	OTHER SYSTEMIC DISEASE LIKELY TO LIMIT OR PRECLUDE SURVIVAL AND REHABILITATION AFTER TRANSPLANTATION	01	02	17 18
46.6	PSYCHIATRIC ILLNESS OR SEVERE BEHAVIORAL DISORDER (SPECIFY NATURE OF DISORDER)_____ _____	01	02	19 20
46.7	PHYSICAL HANDICAP (SPECIFY NATURE OF HANDICAP) _____ _____	01	02	21 22
46.8	RECENT AND UNRESOLVED PULMONARY INFARCTION	01	02	23 24
46.9	INSULIN-REQUIRING DIABETES MELLITUS	01	02	25 26
46.10	SYMPTOMATIC OR DOCUMENTED SEVERE ASYMPTOMATIC PERIPHERAL OR CEREBROVASCULAR DISEASE	01	02	27 28
46.11	ACTIVE PEPTIC ULCER DISEASE	01	02	29 30
46.12	ABSENCE OF ADEQUATE EXTERNAL PSYCHOSOCIAL SUPPORTS	01	02	31 32
46.13	ADVANCING AGE (UNABLE TO WITHSTAND SURGERY OR POSTOPERATIVE COMPLICATIONS)	01	02	33 34

(CIRCLE YES OR NO FOR EACH ITEM)

	YES	NO
46.14 PULMONARY VASCULAR RESISTANCE **GREATER** THAN EIGHT WOOD UNITS	01	02
46.15 DRUG OR ALCOHOL ADDICTION	01	02
46.16 GOOD PROGNOSIS DESPITE CARDIAC DISEASE (BETTER THAN 10-25 PERCENT LIKELIHOOD OF SURVIVING FOR 6 MONTHS)	01	02
46.17 INCOME TOO LOW, PATIENT UNLIKELY TO BE ABLE TO PAY FOR TRANSPLANT OR FOLLOWUP	01	02
46.18 OTHER (SPECIFY) _____	01	02
46.19 OTHER (SPECIFY) _____	01	02
46.20 OTHER (SPECIFY) _____	01	02
46.21 OTHER (SPECIFY) _____	01	02

47. On what date (month/day/year) was this patient turned down as a transplant candidate?

_____/_____/_____
MONTH DAY YEAR

48. To your knowledge, following your evaluation of this patient, did he/she go to another heart transplant program for evaluation with the expressed purpose of receiving a heart transplant?

(CIRCLE ONE)

YES 01

NO ..... 02 **(SKIP TO Q.50)**

49. To what other heart transplant programs do you expect this patient went for evaluation? *(LIST ALL PROGRAMS BY NAME ONLY).*

_____

_____

_____

_____

_____

1 1 4

MORTALITY DATA

50. To your knowledge, has this patient expired?

(CIRCLE ONE)

YES	01	
NO	02	**(SKIP TO Q.55)**
DON'T KNOW	-2	**(SKIP TO Q.55)**

(Dup 1-6)

7 8

51. On what date did this patient expire?

_____

MONTH DAY YEAR

9 14

52. Where did this patient expire?

(CIRCLE ONE)

IN YOUR HOSPITAL	01
IN ANOTHER HOSPITAL	02
OUT OF HOSPITAL BUT IN YOUR CITY	03
OUT OF HOSPITAL–AT PATIENT'S HOME	04
OUT OF HOSPITAL BUT NOT AT HOME	05
DON'T KNOW	-2

15 16

53. To your knowledge, what was the underlying (primary) cause of death of this patient?

_____

UNDERLYING CAUSE OF DEATH

17 20

54. To your knowledge, what were the contributory causes of death for this patient? *(PLEASE LIST UP TO FOUR)*

54.1. _____ 21 — — — 24

54.2. _____ — — — —

54.3. _____ — — — —

54.4. _____ 33 — — — 36

55. On what date did your program last have contact with this patient?

_____/_____/_____ 37 — — — — — 42
MONTH DAY YEAR

78 1 1 5 80

END OF QUESTIONNAIRE –
DO NOT CONTINUE BEYOND THIS PAGE

THESE QUESTIONS ARE ONLY FOR THOSE PATIENTS WHO WERE ACCEPTED AS HEART TRANSPLANT CANDIDATES BUT DIED BEFORE THEY RECEIVED A HEART TRANSPLANT

56. On what date was this patient formally accepted into your program as a heart transplant candidate?

(Dup 1-6)

_____ / _____ / _____

MONTH DAY YEAR

7 — — — — — — 12

MORTALITY DATA

57. On what date did this patient expire?

_____ / _____ / _____

MONTH DAY YEAR

13 — — — — — — 18

58. Where did this patient expire?

(CIRCLE ONE)

IN YOUR HOSPITAL 01

IN ANOTHER HOSPITAL 02

OUT OF HOSPITAL BUT IN YOUR CITY 03

OUT OF HOSPITAL—AT PATIENT'S HOME 04

OUT OF HOSPITAL BUT NOT AT HOME 05

UNKNOWN 06

19 — 20

59. On what date did your program last have contact with this patient?

_____ / _____ / _____

MONTH DAY YEAR

21 — — — — — — 26

60. To your knowledge, what was the underlying (primary) cause of death of this patient?

_____

UNDERLYING CAUSE OF DEATH

27 — — — 30

61. To your knowledge, what were the contributory causes of death for this patient? *(PLEASE LIST UP TO FOUR)*

61.1. _____ 31 34

61.2. _____

61.3. _____

61.4. _____ 43 46

62. Was the patient accepted into your program as a heart transplant candidate (see Question 56, above) between January 1, 1978 and June 30, 1983?

(CIRCLE ONE)

YES ..... 01 **(GO TO Q.63)** 47 48

NO ..... 02 **(STOP. END OF QUESTIONNAIRE.)**

1 1 6 78 80

CANDIDACY PERIOD FINANCIAL DATA

3. Between the time a patient is accepted as a heart transplant candidate and the time of their death, they may have incurred medical expenses. For this patient's **CANDIDACY** period, we would like you to assemble and summarize all data on medical expenses this patient may have incurred at your institution between the date he/she was accepted as a heart transplant candidate and the date of their death.

ITEM OR SERVICE	CHARGE
A. MEDICAL, SURGICAL, AND CENTRAL SUPPLIES	
A.1. MEDICAL SUPPLIES	$_____
A.2. SURGICAL SUPPLIES	$_____
A.3. CENTRAL SUPPLIES	$_____
A.4. OTHER SUPPLIES	$_____
A.5. TOTAL SUPPLIES (IF AVAILABLE)	$_____
B. OPERATING ROOM AND ANESTHESIA	
B.1. OPERATING ROOM	$_____
B.2. ANESTHESIA (EXCLUDING PROFESSIONAL TIME)	$_____
B.3. OTHER (SPECIFY) _____	$_____
B.4. TOTAL OPERATING ROOM AND ANESTHESIA (IF AVAILABLE)	$_____

(Dup 1-6)

7 — — — — 11

— — — — —

17 — — — — 21

— — — — —

27 — — — — — 32

— — — — —

38 — — — — 42

— — — — —

48 — — — — — 53

1 1 7
78 80

ITEM OR SERVICE (Continued)	CHARGE
C. PHARMACY	
C.1. DRUGS, IN-HOSPITAL	$_____
C.2. DRUGS, TAKE-HOME OR DISCHARGE	$_____
C.3. I.V. SOLUTIONS	$_____
C.4. ALL OTHER DRUGS	$_____
C.5. TOTAL PHARMACY (IF AVAILABLE)	$_____
D. THERAPY	
D.1. RESPIRATORY/INHALATION THERAPY	$_____
D.2. VOCATIONAL/OCCUPATIONAL THERAPY	$_____
D.3. PHYSICAL THERAPY/PHYSICAL MEDICINE	$_____
D.4. OTHER THERAPY	$_____
D.5. TOTAL THERAPY (IF AVAILABLE)	$_____
E. APPLIANCES	$_____
F. DIAGNOSTIC TESTS	
F.1. EKG	$_____
F.2. CARDIAC MONITORING/CARDIAC CATH LAB	$_____
F.3. RADIOLOGY (X-RAY)	$_____
F.4. RADIATION MEDICINE	$_____
F.5. NUCLEAR MEDICINE	$_____
F.6. INFECTIOUS DISEASE	$_____
F.7. SURGICAL PATHOLOGY	$_____
F.8. OTHER DIAGNOSTIC TESTS	$_____
F.9. TOTAL DIAGNOSTIC TESTS (IF AVAILABLE)	$_____

(Dup 1-6)

(Dup 1-6)

ITEM OR SERVICE (Continued)	CHARGE	
G. BLOOD ADMINISTRATION		(Dup 1-6)
G.1. BLOOD TRANSFUSION	$_____	7 — — — — 11
G.2. BLOOD BANK	$_____	— — — — —
G.3. COAGULATION LABORATORY	$_____	17 — — — — 21
G.4. BLOOD PROCESSING	$_____	— — — — —
G.5. BLOOD PLASMA (PROC)	$_____	27 — — — — 31
G.6. BLOOD ADMINISTRATION	$_____	— — — — —
G.7. BLOOD LAB	$_____	37 — — — — 41
G.8. OTHER (SPECIFY) _____	$_____	— — — — —
G.9. TOTAL BLOOD AND ADMINISTRATION (IF AVAILABLE)	$_____	47 — — — — 52
H. OXYGEN AND GAS MIXTURES	$_____	53 — — — — 58
		78 **1 2 0** 80
I. LABORATORY TESTS		(Dup 1-6)
I.1. HEMATOLOGY	$_____	7 — — — — 11
I.2. CHEMISTRY	$_____	— — — — —
I.3. IMMUNOLOGY/IMMUNOPATHOLOGY	$_____	17 — — — — 21
I.4. PULMONARY PHYSIOLOGY	$_____	— — — — —
I.5. VIROLOGY	$_____	27 — — — — 31
I.6. MICROBIOLOGY	$_____	— — — — —
I.7. DRUG ASSAY	$_____	37 — — — — 41
I.8. CLINICAL LABORATORY TESTS (IF GIVEN)	$_____	— — — — —
I.9. PATHOLOGY LABORATORY TESTS (IF GIVEN)	$_____	47 — — — — 51
I.10. ICU LABORATORY TESTS	$_____	— — — — —
I.11. OTHER LABORATORY TESTS	$_____	57 — — — — 61
I.12. TOTAL LABORATORY TESTS (IF AVAILABLE)	$_____	78 **1 2 1** 80

ITEM OR SERVICE (Continued)	CHARGE	(Dup 1-6)
J. OTHER SERVICES	$_____	7 — — — — — 12
K. MISCELLANEOUS	$_____	13 — — — — — 18
L. PROFESSIONAL FEES		
L.1. ANESTHESIOLOGY	$_____	19 — — — — — 23
L.2. CARDIOLOGY	$_____	— — — — —
L.3. SURGERY	$_____	29 — — — — — 33
L.4. RADIOLOGY	$_____	— — — — —
L.5. PULMONARY PHYSICIAN	$_____	39 — — — — — 43
L.6. OCCUPATIONAL THERAPIST	$_____	— — — — —
L.7. OTHER (SPECIFY) _____	$_____	49 — — — — — 53
L.8. OTHER (SPECIFY) _____	$_____	— — — — —
L.9. OTHER (SPECIFY) _____	$_____	59 — — — — — 63
L.10. OTHER (SPECIFY) _____	$_____	— — — — —
L.11. TOTAL PROFESSIONAL FEES (IF AVAILABLE)	$_____	69 — — — — — 74
		1 2 2 78 80

ITEM OR SERVICE (Continued)	CHARGE
M. ROOM AND BOARD	
M.1. ICU (SURGICAL)	$_____
M.2. ICU (OTHER)	$_____
M.3. CCU	$_____
M.4. GENERAL WARD (PRIVATE)	$_____
M.5. GENERAL WARD (SEMI-PRIVATE)	$_____
M.6. GENERAL WARD (OTHER)	$_____
M.7. OTHER (SPECIFY) _____	$_____
M.8. TOTAL ROOM AND BOARD (IF AVAILABLE)	$_____
GRAND TOTAL	$_____

(Dup 1-6)

7 — — — — 11

— — — — —

17 — — — — 21

— — — — —

27 — — — — 31

— — — — —

37 — — — — 41

42 — — — — — 47

48 — — — — — 53

1 2 3

78 80

64. During the time this patient was awaiting a suitable donor heart, that is, the period **following their evaluation** up until the day they expired, how many days did he/she spend in the ICU, CCU, and general ward at your institution?

	ROOM	NUMBER OF DAYS	(Dup 1-6)
64.1	ICU (SURGICAL)	_____	— — — (7–9)
64.2	ICU (OTHER)	_____	— — —
64.3	CCU	_____	— — — (13–15)
64.4	GENERAL WARD (PRIVATE)	_____	— — —
64.5	GENERAL WARD (SEMI-PRIVATE)	_____	— — — (19–21)
64.6	GENERAL WARD (OTHER)	_____	— — —
64.7	OTHER (SPECIFY) _____	_____	— — — (25–27)

65. To whom were charges made for the care of this patient during this period?

a) Please indicate **all** sources of payment

(CIRCLE YES OR NO FOR EACH PAYMENT SOURCE)

		YES	NO	
65.1	SELF-PAY	01	02	28 29
65.2	OTHER FAMILY MEMBERS	01	02	
65.3	MEDICARE	01	02	32 33
65.4	MEDICAID	01	02	
65.5	CHAMPUS	01	02	36 37
65.6	OTHER GOVERNMENT PROGRAM	01	02	
65.7	BLUE CROSS/BLUE SHIELD	01	02	
65.8	OTHER PRIVATE OR COMMERCIAL INSURANCE	01	02	42 43
65.9	RESEARCH GRANT FUNDS (e.g., NIH)	01	02	
65.10	SPECIAL PATIENT FUND	01	02	46 47
65.11	OTHER ANONYMOUS CONTRIBUTIONS	01	02	
65.12	OTHER (SPECIFY) _____	01	02	50 51

b) Which of the above was the **principal** source of payment?

_____

PRINCIPAL SOURCE OF PAYMENT 52 53

66. What is the approximate dollar amount of charges paid by each source for this period?

		RECORD DOLLARS
66.1	SELF-PAY	$_____
66.2	OTHER FAMILY MEMBERS	$_____
66.3	MEDICARE	$_____
66.4	MEDICAID	$_____
66.5	CHAMPUS	$_____
66.6	OTHER GOVERNMENT PROGRAM	$_____
66.7	CROSS/BLUE SHIELD	$_____
66.8	PRIVATE OR COMMERCIAL INSURANCE	$_____
66.9	RESEARCH GRANT FUNDS (e.g. NIH)	$_____
66.10	SPECIAL PATIENT FUND	$_____
66.11	OTHER ANONYMOUS CONTRIBUTIONS	$_____
66.12	OTHER (SPECIFY) _____	$_____

67. How much, if any, of this patient's hospital bill for this period was eventually written off by the hospital as bad debt?

BAD DEBT $_____

☐ CHECK IF UNKNOWN

END OF QUESTIONNAIRE --
DO NOT CONTINUE BEYOND THIS PAGE

1 2 4

(Dup 1-6)

1 2 5

THESE QUESTIONS ARE ONLY FOR THOSE LIVING PATIENTS WHO HAVE BEEN EVALUATED AND ACCEPTED FOR A HEART TRANSPLANT BUT ARE AWAITING A SUITABLE DONOR OR THOSE WHO WERE DESELECTED

68. Was the patient deselected as a heart transplant candidate or is he/she currently awaiting a heart transplant?

(Dup 1-6)

(CIRCLE ONE)

DESELECTED 01

AWAITING A TRANSPLANT ..... 02 **(SKIP TO Q.77)**

69. On what date was this patient deselected?

_____

MONTH DAY YEAR

70. Why was this patient deselected?

_____

PRIMARY REASON

MORTALITY DATA

71. Is this patient currently living or deceased?

(CIRCLE ONE)

LIVING ..... 01 **(SKIP TO Q.78)**

DECEASED 02

72. On what date did this patient expire?

_____

MONTH DAY YEAR

73. Where did this patient expire?

(CIRCLE ONE)

IN YOUR HOSPITAL 01

IN ANOTHER HOSPITAL 02

OUT OF HOSPITAL BUT IN YOUR CITY 03

OUT OF HOSPITAL–AT PATIENT'S HOME 04

OUT OF HOSPITAL BUT NOT AT HOME 05

DON'T KNOW ..... -2

74. To your knowledge, what was the underlying (primary) cause of death of this patient?

_____
UNDERLYING CAUSE OF DEATH

75. To your knowledge, what were the contributory causes of death for this patient? *(PLEASE LIST UP TO FOUR)*

75.1. _____

75.2. _____

75.3. _____

75.4. _____

76. On what date did your program last have contact with this patient?

_____
MONTH DAY YEAR

END OF QUESTIONNAIRE –
DO NOT CONTINUE BEYOND THIS PAGE

77. How long has this patient been waiting for a heart transplant?

_____
WEEKS

78. Please circle the number of the statement below which best describes this patient's current condition.

(CIRCLE ONE)

NORMAL: NO COMPLAINTS: NO EVIDENCE OF DISEASE	01
ABLE TO CARRY ON NORMAL ACTIVITY: MINOR SIGNS AND SYMPTOMS OF DISEASE	02
NORMAL ACTIVITY WITH EFFORT: SOME SIGNS AND SYMPTOMS OF DISEASE	03
CARE FOR SELF: UNABLE TO CARRY ON NORMAL ACTIVITY OR DO ACTIVE WORK	04
REQUIRES OCCASIONAL ASSISTANCE BUT IS ABLE TO CARE FOR MOST OF OWN NEEDS	05
REQUIRES CONSIDERABLE ASSISTANCE AND FREQUENT MEDICAL CARE	06
DISABLED: REQUIRES SPECIAL CARE AND ASSISTANCE	07
SEVERELY DISABLED: HOSPITALIZATION IS INDICATED ALTHOUGH DEATH NOT IMMINENT	08
VERY SICK: HOSPITALIZATION NECESSARY	09
MORIBUND: FATAL PROCESSES PROGRESSING RAPIDLY	10

1 2 6

APPENDIX 6-C

PATIENT ROSTER FORM

TRANSPLANT CENTER NAME: _____

HEART TRANSPLANT PATIENT ROSTER

This list should contain the names of all patients transplanted at your center since your transplant program began through June 30, 1983. Patients should be in chronological order according to the date of their most recent transplant. Use as many pages as necessary to list all your patients.

PATIENT NAME (LAST, FIRST)	MONTH AND YEAR OF LAST TRANSPLANT (MO. YEAR)	CURRENT PATIENT AGE (YEARS)	WAS THE PATIENT DISCHARGED FROM THE HOSPITAL ALIVE? (Y/N)	HOW MANY TRANSPLANTS HAS THE PATIENT HAD? (1, 2, 3)	IS THE PATIENT CURRENTLY LIVING OR DECEASED? (L/D)	IF PATIENT IS DECEASED, RECORD DATE OF DEATH (MO. YEAR)

APPENDIX 6-D

AUTHORIZATION FOR REVIEW OF MEDICAL RECORDS AND HOSPITAL BILLING INFORMATION FOR LIVING HEART TRANSPLANT RECIPIENT

NATIONAL HEART TRANSPLANTATION STUDY

AUTHORIZATION FOR REVIEW OF MEDICAL RECORDS AND HOSPITAL BILLING INFORMATION

Name: _____
(Please Print)

Place Transplant Performed: _____

Date Transplant Performed: _____

This form authorizes a data abstractor for the National Heart Transplantation Study being conducted by the Battelle Human Affairs Research Centers in Seattle, Washington, to study the hospital billing records and all or part of the medical records that apply to the treatment of my heart disease, my heart transplant, and any associated care as I have indicated below. (Please mark the appropriate responses.)

Authorization to Review Medical Records

_____ I give my permission to review and, if necessary, to make a copy of the *complete record* of the history of my heart disease and treatment.

_____ I wish to restrict access to my medical records as indicated below:

_____

_____

_____

Authorization to Review Hospital Billing Records

_____ I give my permission to review and, if necessary, make a copy of the hospital billing records pertaining to my treatment for heart disease, my transplant, and any associated care.

Signature: _____ Date _____

This authorization must be signed by the recipient and will be valid for one year from date, unless otherwise directed by the recipient.

OMB 0938-0189
(Exp. 12-83)

APPENDIX 6-E

AUTHORIZATION FOR REVIEW OF MEDICAL RECORDS AND HOSPITAL BILLING INFORMATION FOR FAMILY OR HOUSEHOLD MEMBER OF DECEASED HEART TRANSPLANT RECIPIENT

NATIONAL HEART TRANSPLANTATION STUDY

AUTHORIZATION FOR REVIEW OF MEDICAL RECORDS AND HOSPITAL BILLING INFORMATION

Name: _____
(Please Print)

Relationship to Heart Transplant Recipient: _____

Name of Heart Transplant Recipient: _____
(Please Print)

Place Transplant Performed: _____

Date Transplant Performed: _____

This form authorizes a data abstractor for the National Heart Transplantation Study being conducted by the Battelle Human Affairs Research Centers in Seattle, Washington, to study the hospital billing records and all or part of the medical records that apply to the treatment of the heart disease, the heart transplant, and associated care of the named heart transplant recipient as indicated below. (Please mark the appropriate responses.)

Authorization to Review Medical Records

_____ I give my permission to review and, if necessary, to make a copy of the *complete record* of the history of the heart disease and treatment of the named heart transplant recipient.

_____ I wish to restrict access to the medical records as indicated below:

_____

_____

_____

Authorization to Review Hospital Billing Records

_____ I give my permission to review and, if necessary, make a copy of the hospital billing records pertaining to the treatment for heart disease, the transplant, and any associated care of the named heart transplant recipient.

Signature: _____ Date _____

This authorization must be signed by a family or household member of the heart transplant recipient and will be valid for one year from date, unless otherwise directed by the family or household member.

OMB 0938-0189
(Exp. 12/83)

CHAPTER 7

THE SURVEYS OF FAMILY AND HOUSEHOLD MEMBERS

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A. INTRODUCTION

An essential component of the National Heart Transplantation Study involved an examination of the impact of the heart transplant on the quality of life of the transplant recipient and his or her family. Some information regarding the economic costs of transplantation was provided by transplant centers. However, vital information such as measures of patient disability and rehabilitation, social and economic costs of transplantation and the impact of this procedure on the recipients and their families cannot be obtained through hospital records.

Much of this information was obtained through a survey of living heart transplant recipients. However, in addition to obtaining information directly from recipients, a family or household member close to the recipient was also surveyed to obtain his or her perception of the impact of transplantation. The Family or Household Member Questionnaire focused on the impact of transplantation on quality of life, family functioning and family relations. Similar questions were asked of both close family members and transplant recipients, allowing us to examine the impact from two different perspectives.

Data were also obtained from a group of family members or persons who were very familiar with deceased heart transplant recipients. In addition to providing information on the impact of heart transplantation on family relations, this survey provided additional data on the sociomedical status of heart transplant recipients and the social and economic costs and benefits of transplantation. More specifically, this survey instrument focused on these major areas concerning the

heart transplant recipient: sociodemographic variables, the recipient's level of rehabilitation, work history, experiences with social services, and the financial impact of the transplant.

This chapter describes the procedures which were used in conducting the Family and Household Member Surveys. Chapter 5 provides a description of the procedures which were used in administering the Heart Transplant Recipient Survey. The abstraction of information from the medical and hospital records of heart transplant recipients is described in Chapter 6.

B. THE FAMILY AND HOUSEHOLD MEMBER SURVEYS

Two different survey instruments were designed and used to obtain information from family and household members of heart transplant recipients. The first survey was administered to family and household members of living heart transplant recipients. This survey was closely coordinated with the heart transplant recipient survey. The second survey--the survey of family and household members of deceased heart transplant recipients--was conducted using similar survey procedures. These two surveys provide information on the impact of heart transplantation on family relations from two very different perspectives. As such, they provide an opportunity for a more comprehensive analysis of the impact of heart transplantation on transplant recipients and their families.

1. SAMPLE DESIGN

As discussed in Chapter 5, sampling from the universe of living heart transplant recipients from the six participating centers was unnecessary given their small number. With the exception of

patients under 18 years of age and those currently residing outside the United States, all persons who had received heart transplants at the six centers and who were still living were considered eligible for the study. For each transplant recipient who agreed to participate in the study, one family or household member was identified to complete the Family or Household Member Survey (Form A) (see Appendix 7-A). Preferably this person resided with the recipient, however, this was not so in some cases. In most instances the family member surveyed was the spouse of the recipient. For unmarried recipients, the respondent was either a parent, sibling, an adult child, a close relative or an unrelated individual sharing the same household with the recipient.

The initial plan for surveying the families of deceased heart transplant recipients involved drawing a random sample of 100 family or household members from the total universe of families. However, many of the topics addressed in the Family or Household Member Survey (Form B) (see Appendix 7-B) focused on the recipient's level of rehabilitation following transplantation. For this reason we decided to survey family and household members of only those heart transplant recipients who were discharged from the hospital alive following the transplant operation. Of the 252 deceased heart transplant recipients, 132 were discharged from the hospital and returned home following their heart transplant. Transplant center staff members at each center identified those individuals who had the most contact with the recipient. Of these, 94 family or household members of the deceased recipients were located by the transplant centers and initially agreed to participate. Since this group was smaller than

the proposed sample size of 100, there was no need to select a random sample. In most instances the respondent had shared the same household with the transplant recipient at the time of the transplant. The person surveyed was generally the recipient's spouse. For unmarried individuals the person surveyed was a parent, a sibling, an adult child, another close relative, or an unrelated individual sharing the same household with the recipient.

2. CONTENT OF THE FAMILY OR HOUSEHOLD MEMBER SURVEY (FORM A)

The Family or Household Member Survey (Form A) was developed to obtain information about the impact of heart transplantation from the point of view of family or household members of living transplant recipients. Many of the questions were identical to those asked in the Heart Transplant Recipient Survey (discussed in Chapter 5) and in the National Kidney Dialysis and Kidney Transplantation Study Patient Interview (conducted by Battelle in 1982-83).

In addition to information on age, sex and relationship to the heart transplant recipient, respondents were asked general questions relating to their satisfaction with life. The questionnaire also contained specific questions concerning family relations and the manner in which the transplant had affected themselves and other members of the family. Specific topics addressed included:

- length of relationship and frequency of contact with the heart transplant recipient
- current employment status of the respondent and the possible changes in employment status directly related to the transplant
- respondent's feeling of well-being and satisfaction with life in general

- family relations in the recipient's immediate family
- the impact of the recipient's heart condition and transplant on family relations
- the impact of the transplant on marital relations (if the respondent was the spouse of the transplant recipient)
- worry, resentment and other problems that may have resulted from the transplant
- the accuracy of information regarding the heart transplant procedure and the costs which were provided by the transplant center prior to the transplant

3. CONTENT OF THE FAMILY OR HOUSEHOLD MEMBER SURVEY (FORM B)

The Family or Household Member Survey (Form B) was developed to obtain data about the impact of heart transplantation on the quality of life and family relations of those heart transplant recipients who were discharged from the hospital and died thereafter. Consideration was given to topics that could be covered in a questionnaire designed for family or household members who had varying degrees of contact with, and knowledge of, the deceased transplant recipients.

The survey included questions concerning sociodemographic variables and characteristics of the deceased patient's family and household. We were also particularly interested in the patient's level of rehabilitation following the operation, and the financial impact of the heart transplant. More specifically, questions examined:

- limitations of daily activities in the period following and one year prior to the transplantation
- the employment status of the recipient following the transplant and his/her work history five years prior to the operation

- the recipient's experiences with various government programs and rehabilitation services
- the financial impact of heart transplantation

This questionnaire also contained many of the same questions that were asked of family or household members of living heart transplant recipients. In addition to information on age, sex, and the relationships to the recipient, respondents were asked a series of questions which focused on family relations, and the manner in which the transplant affected themselves and other family members. Specific topics which were addressed included:

- length of relationship and frequency of contact with the heart transplant recipient
- employment status of the respondent prior to the recipient's transplant and possible changes in employment status directly related to the transplant
- family relations in the recipient's immediate family around the time of the transplant
- the impact of the transplant on marital relations (if the respondent was the spouse of the transplant recipient)
- the accuracy of information regarding the heart transplant procedure and the costs which were provided by the transplant center prior to the transplant
- the current general financial situation of the respondent

4. PRETEST

In order to evaluate the survey instruments--to identify potential problems of wording, sequencing or the sensitivity of particular questions--pretests of the questionnaires were conducted. The Family and Household Member Survey (Form A) was administered to a

family member of each of the six living transplant recipients who pretested the recipient questionnaire as described in Chapter 5. During the pretest, exact study procedures were followed, with the exception that several key investigators met with the pretest subjects at their homes or at Stanford during a followup visit. The purpose of these meetings was to debrief patients on their experiences in completing the survey, and to determine how comfortable they were with the survey procedures. The pretest subjects reported that it took approximately 15 minutes to complete the questionnaire and that they had little difficulty answering the questions.

A pretest of the Family and Household Member Survey (Form B) was completed with five family members of deceased transplant recipients who were contacted by the Stanford transplant center staff. During the pretest exact study procedures were followed with mailing the survey packets and telephone follow-up one week later. After the completed questionnaires were returned to Battelle, a senior investigator telephoned the respondents to debrief them on their experiences with filling out the questionnaire, and to determine how comfortable they were with the survey and the procedures followed. These family members reported that it took approximately 25 minutes to complete the questionnaire. Comments and suggestions from these family members were particularly valuable in reassuring the research staff that while the topics covered in the survey might be cause for reflection, the overall impact of completing the questionnaire was not unduly upsetting or stressful.

5. SURVEY PROTOCOL

Given the wide geographic distribution of living heart transplant recipients (see Table 7-1), a new technique was developed for data collection. We refer to this technique as the "telephone-assisted mail survey." We developed the technique because of our concern about overall data collection costs. With transplant recipients living in 37 different states, in-person interviews would have been prohibitively expensive. To our knowledge, the technique, developed specifically for the National Heart Transplantation Study, has not been applied previously elsewhere. The survey protocol described below proved to be an effective means of data collection for the widely dispersed group of heart transplant recipients and their families who participated in the study.

The survey and data processing protocol consisted of three steps: (1) initial contact with the family or household members of heart transplant recipients, (2) data collection, and (3) data processing. As described in Chapter 5, each heart transplant center was asked to provide us with a complete roster of all heart transplant recipients, with an indication of whether each recipient was living or deceased. A copy of the form on which the patient rosters were recorded is attached as Appendix 7-C. Excluding patients under 18 and patients residing outside the U.S., we assigned study identification numbers to each recipient and compiled lists of the recipients to be contacted for participation in the study. A staff member from each transplant center then telephoned the eligible heart transplant recipients to seek their participation in the study. If they agreed

Table 7-1
Residences of Living Heart Transplant Recipients Who Participated in the Study, by State

STATE	NUMBER RECIPIENTS
Arizona	13
Arkansas	1
California	47
Connecticut	1
District of Columbia	1
Delaware	1
Florida	6
Georgia	2
Illinois	5
Indiana	4
Iowa	2
Kentucky	1
Maryland	2
Massachusetts	1
Michigan	2
Minnesota	3
Missouri	2
Nevada	1
New Hampshire	1
New Jersey	3
New Mexico	3
New York	7
North Carolina	1
North Dakota	1
Ohio	6
Oklahoma	1
Pennsylvania	23
Rhode Island	1
South Dakota	2
Tennessee	5
Texas	7
Vermont	2
Virginia	3
Washington	2
West Virginia	2
Wisconsin	6
Wyoming	1
TOTAL	172

to participate, they were asked to identify a specific family or household member to complete a family or household member questionnaire. When possible, the family or household members' participation was solicited during the initial phone call to the recipient. Otherwise, the transplant center staff member telephoned the identified family or household members separately to explain the study to seek their cooperation. Based on these initial phone calls, the staff member completed a General Information Form for Family or Household Member Respondents of Living Transplant Recipients (see Appendix 7-D) for each recipient. This form provided Battelle with the name, address, phone number, verbal consent to participate, and relationship of the recipient to the listed family or household member. In this way, lists of participating family or household members of living recipients from each center were compiled for use in the data collection.

Similar procedures were used in contacting family and household members of deceased heart transplant recipients. As described above, we assigned identification numbers to each deceased transplant recipient, and compiled lists of those recipients whose family members were to be contacted for participation in the study. Family members of recipients who were <u>not</u> discharged from the hospital alive following the transplant procedure were not included in the survey. A member of the transplant center staff then made the initial contact with the prospective respondents and completed a General Information Form for Family or Household Respondents of Deceased Recipients (see Appendix 7-E). These forms provided Battelle with the name, address, phone number, verbal consent to participate, and

relationship of the respondent to the deceased recipient. From these forms, lists of participating family or household members of deceased recipients from each center were compiled for use in the data collection.

A contact form was then established for each family or household member. The form was used to record all dates and reasons for communication with the respondent, as well as the date the survey packet was mailed and the date it was returned (see Appendix 7-F). Consideration was given to devising a practical time schedule for sending survey packets to family or household members. Survey materials were mailed to the family or household member of a living transplant recipient one week after the recipient's questionnaire was returned to Battelle. This sequence was used for the following reasons: (1) to ensure that the recipient was participating before requesting the family or household member to complete the questionnaire, (2) to discourage discussion and collaboration between the recipient and the family or household member while filling out their respective questionnaires, and (3) to create a manageable schedule for the telephone call-backs performed by the research assistants. Family or household members of deceased transplant recipients were sent survey packets as the transplant centers provided Battelle with the general information forms described above. Survey materials, however, were not sent during the last half of December. This exception was made because, in general, the response rate of surveys is lower at that time of year. Also, in this particular case we did not wish to add to what might be an emotionally difficult time of year for the families of deceased recipients.

The survey packets were sent to all family or household members who agreed to participate in the study. The packets contained (1) a general consent form to be signed by the respondent (see Appendix 7-G), (2) (for family or household members of deceased recipients), a consent form authorizing the review of medical records and hospital billing information to be signed by the respondent (see Appendix 7-H), (3) a request form for a summary of study results (see Appendix 7-I), (4) a small return envelope for the consent forms and the request form, (5) a Family or Household Member Survey (Form A or Form B) stamped with the recipient's study identification number, (6) a large return envelope for the questionnaire, and (7) a cover letter (see Appendices 7-J and 7-K). This letter explained the purpose of the study, gave instructions for completing and returning the survey materials, and told respondents to expect a telephone call from a survey specialist at Battelle approximately one week after receiving the survey materials. The purpose of this call was to confirm that the respondents had received the packet and answer any questions that arose while the patient was completing the questionnaire. The letter also encouraged respondents to call Battelle collect if they had any questions, giving them the name and telephone number of persons to contact.

Four survey specialists were assigned to be the contact persons for each of the transplant centers. Each specialist was designated with specific responsibility for each center. The assignments were as follows:

- Arizona Health Sciences Center — Judith Raab
- Columbia Presbyterian Medical Center — Judith Raab

. Medical College of Virginia	Lair Showalter
. University of Minnesota	Cynthia Livak
. University of Pittsburgh	Lisa Bowen
. Stanford University Medical Center	Lisa Bowen, Cynthia Livak, Judith Raab, Lair Showalter

Each specialist contacted the family or household members from their assigned centers to answer any questions approximately one week after the survey packets were mailed. If the respondent had received the packet, but had not yet looked at it, a time in the next week was decided upon for the specialist to call again. If the respondent had not received the survey packet, another packet was sent. As completed questionnaires were returned by respondents, the date received was recorded on the contact form. The data was also stamped on the questionnaire, consent forms, and the request for survey results. To maintain anonymity, consent forms and requests for study results were returned to Battelle in separate envelopes and filed separately from the questionnaires. From the first mailing of packets to the keypunching of data, charts were used to record the stages of data collection as they were completed.

The returned questionnaires were coded and edited manually by the assigned survey specialist soon after they were received. Because the questionnaire consisted primarily of closed-ended items that were precoded, coding efforts and potential transcription errors were minimized. Quality control was maintained through weekly meetings to discuss questions, resolve problems, and amend the coding key as necessary. To solve problems of incomplete information, phone calls

were made to the respondents. If completed questionnaires were not received within three weeks, additional phone calls were made to answer questions and encourage respondents to complete and return the questionnaire. Thus, every effort was taken to make the data as complete and accurate as possible.

When the majority of questionnaires had been received and coded, and questions had been resolved through phone calls to the respondents, the survey specialists verified each others' work and resolved discrepancies in coding. The verified instruments were then keypunched and 100% verified, a computer data file was created and the data were cleaned for analysis.

5. CONSENT AND CONFIDENTIALITY PROCEDURES

As described above, initial contact with the family or household members of heart transplant recipients was made by a member of the transplant center staff. Only those individuals who gave their verbal consent to participate were sent survey materials.

As noted above, prior to completing the questionnaire, family or household members of both living and deceased transplant recipients were asked to sign a consent form acknowledging their willingness to participate in the study (General Recipient Consent Form). The family members of deceased recipients were asked to sign a second form granting permission to extract relevant information from the deceased recipient's medical records (Authorization For Review of Medical Records and Hospital Billing Information). Respondents were fully informed of the nature and purposes of the study and the uses which were to be made of the data. The consent forms provided Battelle with

a written acknowledgement from each individual indicating that they have been informed of:

- the objectives of the study
- the procedures to be followed
- measures to be taken to ensure the information they provide is kept confidential
- possible discomforts or risks associated with their participation
- where to direct their inquiries concerning the study
- the purely voluntary nature of their participation and their freedom to refuse any part or discontinue participation in the study at any time.

In a cover letter, respondents were requested to carefully read, and if willing to participate, sign the consent forms and return them to Battelle separately from the survey instrument.

While they were signed by the participant, the consent forms did not contain the participant's identification number. The family or household member questionnaire was the only component of the packet marked with the participant's identification number. It did not, however, ask for the participant's name, address, or other information which could be used to directly identify individuals or link their identification numbers with their names.

When returned, the completed questionnaires were filed separately from the consent forms. Except when necessary to match individual information, the lists of participants and their corresponding identification numbers were kept separately from all data files. All records were maintained in secure storage areas that

were accessible only to authorized personnel. The resulting data files identified participants only by identification number. This procedure has protected the anonymity of the participant's questionnaire responses and all other information obtained concerning the recipient.

C. RESPONSE RATES

Response rates to both the Family or Household Member Surveys were very good and, thus, our initial experience with the telephone-assisted mail survey technique was quite favorable. As indicated by Table 7-2, 152 recipient questionnaires were completed and returned. Out of the 152 family or household members contacted by the respective transplant center staff, only two refused to participate. Four of the recipient questionnaires were returned too close to the deadline for data processing to allow for the mailing of the corresponding family or household member questionnaires. One hundred-forty-six (146) forms were actually sent to the identified respondents. Three of the 146 refused to participate after receiving the questionnaire, and two questionnaires were apparently lost in the mail. In total, of the forms which were sent, 11 were not returned to Battelle. Therefore, of the 146 family or household member forms mailed to respondents, 135 completed questionnaires were returned, resulting in a response rate of 92.5 percent.

Due to the sensitive nature of many of the survey questions, the response rate to the family or household member survey of deceased recipients was not as high as the response rate to the family or household member survey of living recipients. As shown in Table 7-3,

Table 7-2
Family or Household Member Questionnaire (Living Heart Transplant Recipient)

Center	Completed Recipient Questionnaire Returned	Recipient Questionnaire Returned Too Late	Family Member Refused Participate	Number of Questionnaires Mailed	Refused After Receiving Questionnaire	Lost In Mail	Failed to Return Questionnaire	Completed Questionnaire Returned
Arizona	15	0	0	15	0	0	0	15
Columbia	7	0	0	7	0	1	0	6
MCV	14	0	0	14	1	0	0	13
Minnesota	8	0	0	8	0	0	0	8
Pittsburg	25	0	1	24	0	0	1	23
Stanford	83	4	1	78	2	1	5	70
TOTAL	152	4	2	146	3	2	6	135

Table 7-3
Family or Household Member Questionnaire (Deceased Heart Transplant Recipient)

Center	Total Number Deceased Recipients	Number Who Came Home From Hospital	General Information Form Not Returned	Unable to Contact/ Refused to Participate	Number Questionnaires Mailed	Refused After Receiving Questionnaire	Failed to Return Questionnaire	Completed Questionnaire Returned
Arizona	18	10	6	0	4	0	0	4
Columbia	20	5	2	0	3	0	0	3
MCV	20	10	0	0	10	0	0	10
Minnesota	11	2	0	0	2	0	0	2
Pittsburgh	21	9	0	0	9	1	2	6
Stanford	162	96	13	17	66	4	19	43
TOTAL	252	132	21	17	94	5	21	68

of 252 deceased recipients, only 132 were discharged from the hospital alive and returned home following the transplant procedure. Twenty-one (21) General Information forms were not returned by the transplant centers, and 17 respondents either refused to participate or were not reached by the transplant center staff. Therefore, of a possible 132 potential respondents, 94 were sent questionnaires. Five families refused to participate after receiving the questionnaire and 21 questionnaires were never returned. A total of 68 questionnaires were completed and returned to Battelle for analysis, resulting in a 72.3 percent response rate.

D. CONCLUSION

The examination of the impact of transplantation on transplant recipients and their families was a vital component of the National Heart Transplantation Study. To date, only a limited number of studies have reviewed this aspect of transplantation and these studies have virtually ignored the impact of the transplant procedure on family relations.

Response rates were relatively high and respondents' comments indicated a favorable response to the questionnaire, with many expressing appreciation that a study of this nature was being conducted. It should be noted that without their participation, completion of this segment of the study would not have been possible.

APPENDIX 7-A

FAMILY OR HOUSEHOLD MEMBER SURVEY (FORM A)

FAMILY OR HOUSEHOLD MEMBER QUESTIONNAIRE

FORM A

NATIONAL HEART TRANSPLANTATION STUDY*

Health and Population Study Center
Battelle Human Affairs Research Centers
4000 N.E. 41st Street
Seattle, Washington 98105
Telephone (206) 525-3130

* A project sponsored by the Office of Research and Demonstrations of the Health Care Financing Administration. Contract No. 500-81-0051. Questions concerning this study should be directed to Dr. Roger W. Evans at the Battelle Human Affairs Research Centers.

OMB 0938 0189
(Exp. 12 83)

INTRODUCTION TO THE QUESTIONNAIRE

As you are now aware, the National Heart Transplantation Study is the first major study of heart transplant recipients and their family or household members. The study is concerned not only with the financial aspects, but with all aspects of heart transplantation including how well transplant recipients and their families are doing at this time. For clarity, we at the Battelle Human Affairs Research Centers in Seattle, Washington have divided the study into several major research components. These components include: (1) the need for or number of people requiring heart transplants in the United States, (2) the demonstrated value of heart transplantation as a medical procedure, (3) the availability of donor hearts, (4) the cost of performing a heart transplant and the routine medical management that occurs thereafter, (5) the quality of life enjoyed by heart transplant recipients both before and after their heart transplant, and (6) various legal and ethical dilemmas that surround heart transplantation as a medical procedure not suitable for everyone.

The Federal government is currently considering the possibility of extending various benefits to patients who in the future may need a heart transplant. In order to fully understand the implications of doing so, the U.S. Congress mandated that a thorough study of heart transplantation be undertaken. You are being asked to participate in this exceedingly important study along with other family or household members of heart transplant recipients. The National Heart Transplantation Study intends to present an accurate and objective picture of the current status of heart transplantation in the United States. The results of this study are expected to play a key role in decisions Congress will make concerning heart transplantation.

In this questionnaire we are particularly interested in how you and others close to the heart transplant recipient were affected by the transplant. We recognize that people within the same family do not always agree on everything, especially in a stressful situation such as one created by a severe illness. The focus of this questionnaire, therefore, is on how **YOU** feel about the recipient's heart transplant and how **YOU** have adjusted to it. We ask that you complete the questionnaire **WITHOUT** consulting the recipient since some of these questions have also been asked of him/her.

In responding you may at times wonder about the value of the information you are asked to provide, may dislike the content of some questions, or may feel that some questions are repeated. These responses are not unexpected and merely reflect the complexity of the study in which you are participating. If the questions make you feel too uncomfortable you should place a collect call to Dr. Roger W. Evans at (206) 525-3130. He will be happy to discuss whatever problems you may have in completing the questionnaire.

There may also be some questions which you feel are "none of our business" or that you would prefer not to answer. If you choose not to answer a question for any reason, please indicate this by writing "NO ANSWER" beside the question so we will know that you read the question and decided not to respond. Be assured that **YOU ARE NOT REQUIRED TO ANSWER ANY QUESTION IN THIS QUESTIONNAIRE.** As in any survey, we would like you to answer as many questions as you possibly can. If too many people choose not to answer the questions, the success of the study will be jeopardized.

In order to acknowledge your willingness to participate in the study, we have enclosed a consent form which we would like you to sign. This General Consent Form simply indicates that you are willing to answer the questions in this questionnaire. As noted in the form, all information we receive from you is strictly confidential. No one, including the government or doctors, will ever be told how you responded to the questionnaire. Your name will not appear on the questionnaire. You will notice that a number has been assigned to your questionnaire--this is the **only** identifying information that will be associated with your questionnaire.

Once you have signed the consent form you should retain the pink copy for your records and return the white and yellow copies to us. You should return the completed questionnaire in a separate envelope. The consent form will be retained in a file separate from your questionnaire. More specific information on the anonymity of your responses and the confidentiality of the data is provided in the enclosed consent form.

Within the next seven days, a survey assistant at the Battelle Human Affairs Research Centers will be calling to answer any questions you may have about the National Heart Transplantation Study. It would be helpful if you would complete as much of the questionnaire as you can before you receive the call. If, however, you have questions or are particularly troubled by the questionnaire, please do not hesitate to place a collect call to us at (206) 525-3130, extension 457. We would be more than happy to discuss the study with you.

FAMILY OR HOUSEHOLD MEMBER NO. _____ 1 2 3 4 5 6

DATE _____ 7 8 9 10 11 12

1. What is your year of birth? 13 14

_____
YEAR

2. What is your sex?

(CIRCLE ONE)

MALE 01

FEMALE 02 15 16

3. What is your relationship to the heart transplant recipient?

(CIRCLE ONE)

SPOUSE 01

PARENT 02

SON/DAUGHTER 03 17 18

BROTHER/SISTER 04

OTHER RELATIVE (SPECIFY) _____ ... 05

OTHER (SPECIFY) _____ ... 06

4. Are you currently living with the recipient?

(CIRCLE ONE)

YES 01

NO 02 19 20

5. **IF NO,** how often do you see the recipient?

(CIRCLE ONE)

EVERY DAY 01
SEVERAL DAYS A WEEK 02
ABOUT ONCE A WEEK 03
2 OR 3 TIMES A MONTH 04
ABOUT ONCE A MONTH 05
5 TO 10 TIMES A YEAR 06
LESS THAN 5 TIMES A YEAR 07

21 22

6. How long have you known the recipient?

_____ YEARS

23 24

7. What is your **CURRENT** work activity or employment status?

(CIRCLE ONE)

EMPLOYED FULL-TIME 01
EMPLOYED PART-TIME 02
EMPLOYED BUT TEMPORARILY LAID OFF 03
UNEMPLOYED, LOOKING FOR WORK 04
UNEMPLOYED, NOT LOOKING FOR WORK 05
UNABLE TO WORK BECAUSE OF HEALTH (DISABLED) 06
HOMEMAKER 07
STUDENT (FULL-TIME) 08
RETIRED 09
OTHER (SPECIFY) _____ 10

25 26

8. What was your work activity or employment status **PRIOR** to the recipient's heart transplant?

(CIRCLE ONE)

EMPLOYED FULL-TIME 01

EMPLOYED PART-TIME 02

EMPLOYED BUT TEMPORARILY LAID OFF 03

UNEMPLOYED, LOOKING FOR WORK 04

UNEMPLOYED, NOT LOOKING FOR WORK 05

UNABLE TO WORK BECAUSE OF HEALTH (DISABLED)..... 06

HOMEMAKER 07

STUDENT (FULL-TIME) 08

RETIRED 09

OTHER (SPECIFY) _____ 10

27 28

9. If there has been a change in your employment status since the recipient's heart transplant, was the change directly related to the transplant?

(CIRCLE ONE)

YES 01

NO 02

NO CHANGE 03

29 30

QUALITY OF LIFE

We would like you to answer a few questions about how you have felt and how things have been within the **PAST MONTH.**

10. How have you been feeling in general during the **PAST MONTH?**

(CIRCLE ONE)

IN EXCELLENT SPIRITS 01

IN VERY GOOD SPIRITS 02

IN GOOD SPIRITS MOSTLY 03

UP AND DOWN IN SPIRITS A LOT 04

IN LOW SPIRITS MOSTLY 05

IN VERY LOW SPIRITS 06

11. Have you been bothered by nervousness or your nerves during the **PAST MONTH?**

(CIRCLE ONE)

EXTREMELY SO--TO THE POINT WHERE YOU COULD NOT WORK OR TAKE CARE OF THINGS 01

VERY MUCH SO 02

QUITE A BIT 03

SOME--ENOUGH TO BE BOTHERED 04

A LITTLE 05

NOT AT ALL 06

12. Have you been in firm control of your behavior, thoughts, emotions, **OR** feelings during the **PAST MONTH?**

(CIRCLE ONE)

YES, DEFINITELY SO 01

YES, FOR THE MOST PART 02

GENERALLY SO 03

NOT TOO WELL 04

NO, ENOUGH TO BOTHER YOU SOMEWHAT 05

NO, ENOUGH TO BOTHER YOU VERY MUCH 06

13. Have you felt so sad, discouraged, hopeless or had so many problems that you wondered if anything was worthwhile during the **PAST MONTH?**

(CIRCLE ONE)

EXTREMELY SO—TO THE POINT THAT YOU HAVE JUST ABOUT GIVEN UP 01

VERY MUCH SO 02

QUITE A BIT 03

SOME–ENOUGH TO BE BOTHERED 04

A LITTLE BIT 05

NOT AT ALL 06

14. Have you been under or felt you were under any strain, stress, or pressure during the **PAST MONTH?**

(CIRCLE ONE)

YES–ALMOST MORE PRESSURE THAN YOU COULD BEAR OR STAND	01
YES–QUITE A BIT OF PRESSURE	02
YES–SOME - MORE THAN USUAL	03
YES–SOME - BUT ABOUT USUAL	04
YES–A LITTLE	05
NOT AT ALL	06

15. How happy, satisfied, or pleased have you been with your personal life during the **PAST MONTH?**

(CIRCLE ONE)

EXTREMELY HAPPY–COULD NOT HAVE BEEN MORE SATISFIED OR PLEASED	01
VERY HAPPY	02
FAIRLY HAPPY	03
SATISFIED–PLEASED	04
SOMEWHAT DISSATISFIED	05
VERY DISSATISFIED	06

16. Have you had any reason to wonder if you were losing your mind, or losing control over the way you act, talk, think, or feel during the **PAST MONTH?**

(CIRCLE ONE)

NOT AT ALL 01

ONLY A LITTLE 02

SOME–BUT NOT ENOUGH TO BE CONCERNED OR WORRIED ABOUT 03

SOME AND A LITTLE CONCERNED ABOUT IT 04

SOME AND QUITE CONCERNED ABOUT IT ... 05

YES, VERY MUCH SO AND VERY CONCERNED ABOUT IT 06

17. Have you been anxious, worried, or upset during the **PAST MONTH?**

(CIRCLE ONE)

EXTREMELY SO–TO THE POINT OF BEING SICK OR ALMOST SICK 01

VERY MUCH SO 02

QUITE A BIT 03

SOME–ENOUGH TO BE BOTHERED 04

A LITTLE BIT 05

NOT AT ALL 06

18. Have you felt down-hearted and blue during the **PAST MONTH?**

(CIRCLE ONE)

ALL OF THE TIME 01
MOST OF THE TIME 02
A GOOD BIT OF THE TIME 03
SOME OF THE TIME 04
A LITTLE OF THE TIME 05
NONE OF THE TIME 06

47 48

19. Have you been feeling emotionally stable and sure of yourself during the **PAST MONTH?**

(CIRCLE ONE)

ALL OF THE TIME 01
MOST OF THE TIME 02
A GOOD BIT OF THE TIME 03
SOME OF THE TIME 04
A LITTLE OF THE TIME 05
NONE OF THE TIME 06

49 50

20. Some people feel they can run their lives pretty much the way they want to; others feel the problems of life are sometimes too big for them. Which one are you most like?

(CIRCLE ONE)

CAN RUN OWN LIFE 01
PROBLEMS OF LIFE TOO BIG 02

51 52

21. Up to now, have you been able to satisfy most of your ambitions in life or have you had to settle for less than you hoped for?

(CIRCLE ONE)

SATISFIED MOST AMBITIONS 01

HAVE HAD TO SETTLE FOR LESS 02

53 54

22. Do you think you have had a fair opportunity to make the most of your life or have you been held back in some ways?

(CIRCLE ONE)

HAVE HAD A FAIR OPPORTUNITY 01

HAVE BEEN HELD BACK 02

55 56

23. Compared to **OTHER PEOPLE YOU KNOW,** would you say that you have enjoyed your life up to now more than most people, about the same, or less than most people?

(CIRCLE ONE)

MORE 01

ABOUT THE SAME 02

LESS 03

57 58

24. Taking all things together, how would you say things are these days--would you say you're very happy, pretty happy, or not too happy?

(CIRCLE ONE)

VERY HAPPY 01

PRETTY HAPPY 02

NOT TOO HAPPY 03

59 60

25. The things people have--housing, car, furniture, recreation, and the like--make up their standard of living. Some people are satisfied with their standard of living, others feel it is not as high as they would like. How satisfied are you with your standard of living?

(CIRCLE ONE)

COMPLETELY SATISFIED	01
VERY SATISFIED	02
SATISFIED	03
NEUTRAL	04
DISSATISFIED	05
VERY DISSATISFIED	06
COMPLETELY DISSATISFIED	07

61 62

26. How satisfied are you with your life as a whole these days?

(CIRCLE ONE)

COMPLETELY SATISFIED	01
VERY SATISFIED	02
SATISFIED	03
NEUTRAL	04
DISSATISFIED	05
VERY DISSATISFIED	06
COMPLETELY DISSATISFIED	07

63 64

27. All things considered, how satisfied are you with your family life--the time you spend and the things you do with members of your family?

(CIRCLE ONE)

COMPLETELY SATISFIED	01
VERY SATISFIED	02
SATISFIED	03
NEUTRAL	04
DISSATISFIED	05
VERY DISSATISFIED	06
COMPLETELY DISSATISFIED	07

65 66

28. **(FOR MARRIED OR SEPARATED PERSONS ONLY)**
How satisfied are you with your marriage?

(CIRCLE ONE)

COMPLETELY SATISFIED	01
VERY SATISFIED	02
SATISFIED	03
NEUTRAL	04
DISSATISFIED	05
VERY DISSATISFIED	06
COMPLETELY DISSATISFIED	07

67 68

29. How satisfied are you with your family's situation as far as savings and investments are concerned?

(CIRCLE ONE)

COMPLETELY SATISFIED	01
VERY SATISFIED	02
SATISFIED	03
NEUTRAL	04
DISSATISFIED	05
VERY DISSATISFIED	06
COMPLETELY DISSATISFIED	07

69 70

3 0 1

78 80

FAMILY RELATIONS

We would like to get some idea of how a recipient's heart transplant affects his/her family life. Please answer the following questions concerning the immediate family--that is, those with whom the recipient lives and/or has the most contact. Even if you do not consider yourself a member of the recipient's immediate family, but are familiar with them, we would like you to try to answer these questions to the best of your ability. If you do not feel capable of answering any or all of them, please write in "Don't Know" where applicable.

30. All families are different--some are very close and others are not. Would you say the people in the immediate family are...

(CIRCLE ONE)

(Dup 1-6)

VERY CLOSE 01

PRETTY CLOSE 02

A LITTLE CLOSE, OR 03

NOT AT ALL CLOSE TO EACH OTHER? 04

7 8

31. How well do the people in the family get along together at home?

(CIRCLE ONE)

VERY WELL 01

PRETTY WELL 02

A LITTLE WELL 03

NOT AT ALL WELL 04

9 10

32. How often are there arguments in the family these days?

(CIRCLE ONE)

ALMOST CONSTANTLY 01

OFTEN 02

ONCE IN A WHILE 03

NEVER 04

11 12

33. When a problem comes up in the family, are the people in the immediate family...

(CIRCLE ONE)

VERY WILLING TO HELP OUT 01

SOMEWHAT WILLING 02

A LITTLE WILLING, OR 03

NOT AT ALL WILLING TO HELP OUT? 04

34. How often does the immediate family do things together?

(CIRCLE ONE)

VERY OFTEN 01

SOMETIMES 02

RARELY 03

NEVER 04

35. When it was first known that the recipient needed a heart transplant, was the family...

(CIRCLE ONE)

EXTREMELY WORRIED 01

SOMEWHAT WORRIED 02

A LITTLE WORRIED, OR 03

NOT AT ALL WORRIED? 04

36. How would you characterize the family while the recipient has been sick?

(CIRCLE ONE)

VERY TENSE AND NERVOUS 01

SOMEWHAT TENSE 02

A LITTLE TENSE 03

NOT AT ALL TENSE OR NERVOUS 04

37. How upset or disturbed do you feel the family has been by the recipient's heart condition?

(CIRCLE ONE)

VERY UPSET 01

SOMEWHAT UPSET 02

A LITTLE UPSET 03

NOT AT ALL UPSET 04

21 22

38. Some heart transplant recipients feel that their condition is very demanding of their family's time and energy, while others do not feel this way. Would you say the recipient's heart transplant has taken...

(CIRCLE ONE)

A LOT OF THE FAMILY'S TIME AND ENERGY 01

SOME OF THEIR TIME AND ENERGY, OR 02

A LITTLE OF THEIR TIME AND ENERGY? 03

23 24

39. How often have you felt that the recipient's heart transplant has interfered with the family routine at home?

(CIRCLE ONE)

OFTEN 01

SOMETIMES 02

RARELY 03

NEVER 04

25 26

40. Sometimes families resent it when someone in the family can't carry out their normal activities or if they need extra help. Do you feel the transplant has caused any resentment in the family?

(CIRCLE ONE)

YES 01

NO 02

27 28

41. How much would you say the following people have had to give up because of the heart transplant?

(CIRCLE ONE RESPONSE FOR EACH PERSON)

	VERY MUCH	SOME-WHAT	A LITTLE	NOT AT ALL	DOES NOT APPLY	
A. YOURSELF	01	02	03	04	–	29 30
B. THE HEART TRANSPLANT RECIPIENT	01	02	03	04	–	31 32
C. THE CHILDREN IN THE FAMILY	01	02	03	04	05	33 34

42. How well do you think the family understands how the recipient feels about his/her heart transplant?

(CIRCLE ONE)

VERY WELL 01

SOMEWHAT WELL 02

NOT VERY WELL 03

35 36

43. After having major surgery, people often report that their families watch them too carefully and don't want them to return to all their normal activities, even though the person wants to. Would you say this has been true for the family...

(CIRCLE ONE)

OFTEN 01

SOMETIMES, OR 02

NEVER? 03

37 38

44. How much does the family talk about the transplant?

(CIRCLE ONE)

VERY OFTEN 01

SOMETIMES 02

NEVER 03

39 40

45. How much worry would you say the recipient's transplant causes the family now?

(CIRCLE ONE)

GREAT AMOUNT OF WORRY 01

SOME WORRY 02

A SMALL AMOUNT OF WORRY 03

NO WORRY 04

41 42

46. In terms of other problems the family have faced, has the heart transplant been...

(CIRCLE ONE)

A VERY GREAT PROBLEM 01

SOMEWHAT OF A PROBLEM 02

A SMALL PROBLEM, OR 03

NO PROBLEM AT ALL? 04

43 44

47. Do you think that the recipient's heart transplant in any way brought the family closer together or in any way drew the family apart?

(CIRCLE ONE)

BROUGHT CLOSER TOGETHER 01

DREW FAMILY APART 02

NEITHER 03

48. Do you know any other heart transplant recipients?

(CIRCLE ONE)

YES 01

NO 02

49. **IF YES,** in comparison to families of other heart transplant recipients, do you feel the recipient's family has been more helpful, less helpful, or about average?

(CIRCLE ONE)

MORE HELPFUL 01

LESS HELPFUL 02

ABOUT AVERAGE 03

I DON'T KNOW 04

IF YOU ARE THE RECIPIENT'S SPOUSE, PLEASE ANSWER QUESTIONS 50-53; OTHERWISE, GO TO Q.54

50. How long have you been married to your current spouse?

_____ YEARS

51. Do you think that your spouse's heart transplant places a strain on your marriage?

(CIRCLE ONE)

YES 01

NO 02

53 54

52. How has the heart transplant affected your relationship with your spouse? Do you feel...

(CIRCLE ONE)

CLOSER 01

ABOUT THE SAME, OR 02

LESS CLOSE? 03

55 56

53. How satisfied are you with your relationship with your spouse?

(CIRCLE ONE)

VERY SATISFIED 01

SOMEWHAT SATISFIED 02

NEITHER SATISFIED NOR DISSATISFIED 03

SOMEWHAT DISSATISFIED 04

VERY DISSATISFIED 05

57 58

SPOUSES OF RECIPIENTS, NOW GO TO OVERVIEW SECTION, QUESTION 57.

We are also interested in knowing if your involvement with the heart transplant recipient has affected your own family life in any way. Please answer these questions **if your** immediate family is distinct from the immediate family of the recipient; for example, if you are the recipient's son or daughter and have a spouse and/or children. Otherwise, go to Question 57.

54. Do you think that the recipient's heart transplant in any way brought **your** family closer together or in any way drew your family apart?

(CIRCLE ONE)

BROUGHT CLOSER TOGETHER 01

DREW FAMILY APART 02

NEITHER 03

55. Do you think your involvement with the heart transplant recipient places a strain on **your** family relationships?

(CIRCLE ONE)

YES 01

NO 02

56. Some families feel that the transplant recipient's condition is very demanding of the family's time and energy while others do not feel this way. Would you say the recipient's heart transplant has taken...

(CIRCLE ONE)

A LOT OF **YOUR** FAMILY'S TIME AND ENERGY 01

SOME OF THEIR TIME AND ENERGY, OR 02

A LITTLE OF THEIR TIME AND ENERGY? 03

3 0 2

OVERVIEW

57. Because of the recipient's heart condition, do you think you need...

(CIRCLE ONE)

(Dup 1-6)

A LOT OF EXTRA HELP TO GET THINGS DONE 01

SOME EXTRA HELP TO GET THINGS DONE 02

A LITTLE EXTRA HELP, OR 03

NO MORE HELP THAN ANY HEALTHY PERSON? 04

58. Because of the recipient's heart condition, do you feel you...

(CIRCLE ONE)

ARE MORE DEPENDENT ON OTHERS FOR HELP THAN YOU WOULD LIKE TO BE, OR ... 01

THAT YOU WOULD LIKE TO HAVE SOMEONE YOU COULD DEPEND ON MORE, OR 02

NEITHER? ..... 03 **(GO TO Q.60)**

59. How much of a problem is your dependence upon others since the recipient's heart transplant?

(CIRCLE ONE)

A GREAT PROBLEM 01

SOMEWHAT OF A PROBLEM 02

A SMALL PROBLEM 03

NO PROBLEM 04

60. How worried were you about finances at the time of the transplant?

(CIRCLE ONE)

EXTREMELY WORRIED 01

MODERATELY WORRIED 02

A LITTLE WORRIED 03

NOT AT ALL WORRIED 04

61. How worried are you about your finances now?

(CIRCLE ONE)

EXTREMELY WORRIED 01

MODERATELY WORRIED 02

A LITTLE WORRIED 03

NOT AT ALL WORRIED 04

62. Has the time since the transplant been...

(CIRCLE ONE)

ABOUT WHAT YOU EXPECTED 01

WORSE THAN YOU EXPECTED, OR 02

BETTER THAN YOU EXPECTED? 03

63. Thinking back over the time since the recipient's heart transplant, how often have you felt that it was a mistake?

(CIRCLE ONE)

NEVER 01

ALMOST NEVER 02

SOMETIMES 03

VERY OFTEN 04

ALWAYS 05

64. In general, do you feel that the recipient was well informed by doctors and transplant center staff **BEFORE** the operation about the transplant procedure and recovery?

(CIRCLE ONE)

YES 01

NO 02

21 22

65. Do you think the information on transplant costs the recipient received **PRIOR** to the transplant was accurate?

(CIRCLE ONE)

YES 01

NO 02

NO INFORMATION PROVIDED 03

23 24

3 0 3

78 80

CONCLUSION OF THE QUESTIONNAIRE

We at the Battelle Human Affairs Research Centers very much appreciate the time and effort you have put into this questionnaire. The information you have provided is essential to meeting the objectives of the National Heart Transplantation Study. If you have any comments about this questionnaire, please record them on the following page. Also, if you would like to have a brief summary of the results of the study, which will be available by the end of next year, please fill out the enclosed form which will be filed separately from the questionnaire.

INSTRUCTIONS FOR RETURNING STUDY MATERIALS:

In order to keep your name separate from the questionnaire, we have provided two pre-addressed envelopes. You do **not** have to place postage on these envelopes.

- THE LARGE MANILA ENVELOPE SHOULD CONTAIN **ONLY** THE QUESTIONNAIRE.
- THE SMALLER MANILA ENVELOPE SHOULD CONTAIN THE FOLLOWING:
  - 1 White copy of the General Consent Form
  - 1 Yellow copy of the General Consent Form
  - 1 Request for a summary of the study (optional).

Remember to keep the pink copy of the consent form for your own records.

In closing, if you should have any questions whatsoever, please do not hesitate to make a collect call to Dr. Roger W. Evans' office at (206) 525-3130, extension 457. Once again, we are very grateful for your participation in this very important study.

COMMENTS

Yes, I would like to receive a summary of the National Heart Transplantation Study.

Name _____

Address _____

City _____ State _____ Zip Code _____

APPENDIX 7-B

FAMILY OR HOUSEHOLD MEMBER SURVEY (FORM B)

FAMILY OR HOUSEHOLD MEMBER QUESTIONNAIRE

FORM B

NATIONAL HEART TRANSPLANTATION STUDY*

Health and Population Study Center
Battelle Human Affairs Research Centers
4000 N.E. 41st Street
Seattle, Washington 98105
Telephone (206) 525-3130

* A project sponsored by the Office of Research and Demonstrations of the Health Care Financing Administration. Contract No. 500-81-0051. Questions concerning this study should be directed to Dr. Roger W. Evans at the Battelle Human Affairs Research Centers.

OMB 0938-0189
(Exp. 12/83)

INTRODUCTION TO THE QUESTIONNAIRE

As you are now aware, the National Heart Transplantation Study is the first national study of heart transplantation. The study is concerned with all aspects of heart transplantation. For clarity, we at the Battelle Human Affairs Research Centers in Seattle, Washington have divided the study into several major research components. These components include: (1) the need for or number of people requiring heart transplants in the United States, (2) the demonstrated value of heart transplantation as a medical procedure, (3) the availability of donor hearts, (4) the cost of performing a heart transplant and the routine medical management that occurs thereafter, (5) the quality of life enjoyed by heart transplant recipients both before and after their heart transplant, and (6) various legal and ethical dilemmas that surround heart transplantation as a medical procedure not suitable for everyone.

The Federal government is currently considering the possibility of extending various benefits to patients who in the future may need a heart transplant. In order to fully understand the implications of doing so, the U.S. Congress mandated that a thorough study of heart transplantation be undertaken. You are being asked to participate in this exceedingly important study. The National Heart Transplantation Study intends to present an accurate and objective picture of the current status of heart transplantation in the United States. The results of this study are expected to play a key role in decisions Congress will make concerning heart transplantation.

To meet the numerous and varied objectives of the study as outlined above, this questionnaire was developed. Living heart transplant recipients and their spouses, parents, or other family members are being asked to complete a similar questionnaire. The questions you will be asked concern the heart transplant recipient as well as yourself. We realize this may be difficult for you. However, we feel that only the relative of a deceased heart transplant recipient will be able to provide very important information about certain aspects of their relative's transplant that we would not get otherwise. Under no circumstances do we intend to overburden you with questions that are of little or no value.

We suggest that you make yourself comfortable when you sit down to fill out the questionnaire and thoughtfully answer as many of the questions as you can. Any person whose relative has undergone major surgery or life-saving therapy has undoubtedly given considerable thought to many difficult issues, such as the quality of the person's life, and the impact of their treatment on the family. However, you may not have ever been asked to answer questions addressing these issues in a study such as this. Therefore, you may very well experience some discomfort in doing so. If the questions make you feel too uncomfortable you should place a collect call to Dr. Roger W. Evans at (206) 525-3130. He will be happy to discuss whatever problems you may have in completing the questionnaire.

In responding you may at times wonder about the value of the information you are asked to provide, may dislike the content of some questions, or may feel that some questions are repeated. These responses are not unexpected and merely reflect the complexity of the study in which you are participating. There may also be some questions which you feel are "none of our business" or that you would prefer not to answer. If you choose not to answer a question for any reason, please indicate this by writing "NO ANSWER" beside the question so that we will know that you read the question and decided not to respond. Be assured that **YOU ARE NOT REQUIRED TO ANSWER ANY QUESTION IN THIS QUESTIONNAIRE.** As in any survey, we would like you to answer as many questions as you possibly can. If too many people choose not to answer the questions, the success of the study will be jeopardized.

As in any study of this sort, your participation is purely voluntary. In order to acknowledge your willingness to participate in the study, we have enclosed two consent forms which we would like you to sign. The first consent form is called the General Consent Form and simply indicates that you are willing to answer the questions in this questionnaire. In addition to having you complete the questionnaire we would also like to obtain some information from the heart transplant recipient's medical and hospital records maintained at the transplant center. To give us permission to see his/her medical and hospital records, you must also sign the enclosed form entitled "Authorization for Review of Medical and Hospital Records." If you choose to let us review his/her medical records, only information about the heart transplant will be studied.

As noted in the General Consent Form, all information we receive from you or the heart transplant center is strictly confidential. No one, including the government or the recipient's doctors, will ever be told how you responded to the questionnaire. Your name will not appear on the questionnaire. You will notice that a number has been assigned to your questionnaire--this is the **only** identifying information that will be associated with your questionnaire.

Once you have signed the consent forms you should retain the pink copy for your records and return the white and yellow copies to us. You should return the completed questionnaire in a separate envelope. The consent forms will be retained in a file separate from your questionnaire. More specific information on the anonymity of your responses and the confidentiality of the data is provided in the enclosed consent forms.

Within the next seven days, a survey assistant at the Battelle Human Affairs Research Centers will be calling to answer any questions you may have about the National Heart Transplantation Study. It would be helpful if you would complete as much of the questionnaire as you can before you receive the call. If, however, you have questions or are particularly troubled by the questionnaire, please do not hesitate to place a collect call to Dr. Roger W. Evans' office at (206) 525-3130, extension 457. We would be more than happy to discuss the study with you.

FAMILY OR HOUSEHOLD MEMBER NO. _____ 1 2 3 4 5 6

DATE _____ 7 8 9 10 11 12

1. What is your year of birth?

_____ YEAR 13 14

2. What is your sex?

(CIRCLE ONE)

MALE 01

FEMALE 02 15 16

3. What is your current marital status?

(CIRCLE ONE)

MARRIED 01

WIDOWED 02

DIVORCED 03 17 18

SEPARATED 04

NEVER MARRIED 05

4. What was your relationship to the heart transplant recipient?

(CIRCLE ONE)

SPOUSE 01

PARENT 02

SON/DAUGHTER 03

BROTHER/SISTER 04 19 20

OTHER RELATIVE (SPECIFY) _____ ... 05

OTHER (SPECIFY) _____ ... 06

5. How long did you know the recipient?

_____ YEARS

21 22

6. Did you live with the recipient...

(CIRCLE YES OR NO FOR EACH TIME PERIOD)

	YES	NO
A. DURING THE TIME THE RECIPIENT WAS HOME FOLLOWING THE TRANSPLANT?	01	02
B. DURING THE YEAR PRIOR TO THE TRANSPLANT?	01	02

23 24

25 26

7. **IF NO, TO EITHER A OR B (OR BOTH),** in Question 6, how often did you see the recipient?

(CIRCLE ONE)

EVERY DAY 01

SEVERAL DAYS A WEEK 02

ABOUT ONCE A WEEK 03

2 OR 3 TIMES A MONTH 04

ABOUT ONCE A MONTH 05

5 TO 10 TIMES A YEAR 06

LESS THAN 5 TIMES A YEAR 07

27 28

8. In what month and year was the recipient first diagnosed as having a heart condition?

_____/_____

MONTH YEAR

29 — — — 32

9. When did he/she receive the heart transplant? *(If the recipient had more than one, please enter the date of the most recent transplant.)*

_____/_____/_____

MONTH DAY YEAR

33 — — — — — 38

10. Did he/she have more than one heart transplant?

(CIRCLE ONE)

YES 01

NO ..... 02 — 39 40

11. **IF YES,** how many heart transplants did he/she have?

NUMBER OF TRANSPLANTS _____ — 41 42

12. What was the recipient's year of birth?

_____ YEAR — 43 44

13. Was the recipient male or female?

(CIRCLE ONE)

MALE 01

FEMALE ..... 02 — 45 46

14. Which of the following best describes the recipient's racial or ethnic identification?

(CIRCLE ONE)

BLACK (NEGRO) 01

CHICANO (MEXICAN-AMERICAN) 02

NATIVE AMERICAN (AMERICAN INDIAN, ESKIMO, ALEUT) ..... 03 — 47 48

WHITE (CAUCASIAN) 04

ORIENTAL (ASIAN AMERICAN OR PACIFIC ISLANDER) 05

OTHER (SPECIFY) _____ 06

15. What was his/her marital status at the time of the transplant?

(CIRCLE ONE)

MARRIED 01

WIDOWED 02

DIVORCED 03

SEPARATED 04

NEVER MARRIED 05

49 50

16. How many people lived with the recipient at his/her residence following the transplant?

_____ OTHER RESIDENTS

51 53

17. What type of dwelling did he/she live in following the transplant?

(CIRCLE ONE)

SINGLE FAMILY HOME OWNED BY HIM/HER OR THE FAMILY 01

SINGLE FAMILY HOME RENTED BY HIM/HER OR THE FAMILY 02

UNIT IN A MULTIPLE-FAMILY DWELLING OWNED BY HIM/HER OR THE FAMILY 03

UNIT IN A MULTIPLE-FAMILY DWELLING RENTED BY HIM/HER OR THE FAMILY 04

HOSPITAL 05

NURSING HOME/CONVALESCENT HOME 06

RETIREMENT COMMUNITY 07

OTHER (SPECIFY) _____ 08

54 55

18. Did the recipient have to change his/her residence as a result of the need for a heart transplant?

(CIRCLE ONE)

YES 01

NO ..... 02 **(GO TO Q.21)**

56 57

19. What type of residence did he/she live in before the heart transplant?

(CIRCLE ONE)

SINGLE FAMILY HOME OWNED BY HIM/HER OR THE FAMILY 01

SINGLE FAMILY HOME RENTED BY HIM/HER OR THE FAMILY 02

UNIT IN A MULTIPLE-FAMILY DWELLING OWNED BY HIM/HER OR THE FAMILY 03

58 59

UNIT IN A MULTIPLE-FAMILY DWELLING RENTED BY HIM/HER OR THE FAMILY 04

HOSPITAL 05

RETIREMENT COMMUNITY 06

NURSING HOME/CONVALESCENT HOME 07

OTHER (SPECIFY) _____ 08

20. How was this change in residence related to the heart transplant?

(CIRCLE YES OR NO FOR EACH ITEM)

	YES	NO	
A. NEEDED A LESS EXPENSIVE PLACE BECAUSE OF HIGHER MEDICAL EXPENSES	01	02	60 61
B. NEEDED A RESIDENCE CLOSER TO MEDICAL FACILITIES	01	02	
C. HAD TO CHANGE JOBS AS A RESULT OF THE ILLNESS AND NEEDED A RESIDENCE CLOSER TO WORK	01	02	64 65
D. NEEDED A PLACE EASIER TO MAINTAIN	01	02	
E. NEEDED A RESIDENCE WITH FEWER/NO STAIRS	01	02	68 69
F. OTHER (SPECIFY) _____	01	02	

21. How many years of education did the recipient complete?

_____ YEARS

72 73

4 0 1
78 80

22. What is the highest degree he/she obtained?

(CIRCLE ONE)

(Dup 1-6)

NEVER GRADUATED FROM HIGH SCHOOL 01

HIGH SCHOOL DIPLOMA 02

COLLEGE/UNIVERSITY DEGREE 03

ADVANCED DEGREE (M.A., M.S., Ph.D., M.D., J.D., etc.) 04

— — 7 8

DAILY ACTIVITIES

We are also interested in changes that may have occurred in the recipient's daily activities after he/she received the heart transplant. Some people have found that they could do more than they were doing before their transplant; others had to limit their activities.

Please answer the next questions for two different points in time: (1) the period of time the recipient was **HOME FOLLOWING THE HEART TRANSPLANT, AND** (2) the **YEAR BEFORE** he/she received the **TRANSPLANT.**

23. When traveling around the community, did the recipient need assistance because of health?

(CIRCLE YES OR NO FOR EACH TIME PERIOD)

	YES	NO	
A. TIME AT HOME FOLLOWING TRANSPLANT	01	02	— — 9 10
B. ONE YEAR PRIOR TO TRANSPLANT	01	02	— — 11 12

24. Did he/she have to stay indoors most or all of the day because of health?

(CIRCLE YES OR NO FOR EACH TIME PERIOD)

	YES	NO	
A. TIME AT HOME FOLLOWING TRANSPLANT	01	02	— — 13 14
B. ONE YEAR PRIOR TO TRANSPLANT	01	02	— — 15 16

25. Was he/she in a bed or chair for most or all of the day because of health?

(CIRCLE YES OR NO FOR EACH TIME PERIOD)

	YES	NO	
A. TIME AT HOME FOLLOWING TRANSPLANT	01	02	17 18
B. ONE YEAR PRIOR TO TRANSPLANT	01	02	19 20

26. Did the recipient's health limit the kind of vigorous activities he/she could do?

(CIRCLE YES OR NO FOR EACH TIME PERIOD)

	YES	NO	
A. TIME AT HOME FOLLOWING TRANSPLANT	01	02	21 22
B. ONE YEAR PRIOR TO TRANSPLANT	01	02	23 24

27. Did he/she have any trouble either walking **SEVERAL BLOCKS** or climbing a **FEW FLIGHTS** of stairs because of health?

(CIRCLE YES OR NO FOR EACH TIME PERIOD)

	YES	NO	
A. TIME AT HOME FOLLOWING TRANSPLANT	01	02	25 26
B. ONE YEAR PRIOR TO TRANSPLANT	01	02	27 28

28. Did he/she have trouble bending, lifting, or stooping because of health?

(CIRCLE YES OR NO FOR EACH TIME PERIOD)

	YES	NO	
A. TIME AT HOME FOLLOWING TRANSPLANT	01	02	29 30
B. ONE YEAR PRIOR TO TRANSPLANT	01	02	31 32

29. Did he/she have any trouble either walking **ONE BLOCK** or climbing **ONE FLIGHT** of stairs because of health?

(CIRCLE YES OR NO FOR EACH TIME PERIOD)

	YES	NO	
A. TIME AT HOME FOLLOWING TRANSPLANT	01	02	33 34
B. ONE YEAR PRIOR TO TRANSPLANT	01	02	35 36

30. Did the recipient need help in walking such as assistance by another person or by a cane, crutches, walker, artificial limbs, or braces?

(CIRCLE YES OR NO FOR EACH TIME PERIOD)

	YES	NO	
A. TIME AT HOME FOLLOWING TRANSPLANT	01	02	37 38
B. ONE YEAR PRIOR TO TRANSPLANT	01	02	39 40

31. Was he/she unable to do certain kinds or amounts of work, housework, or schoolwork because of health?

(CIRCLE YES OR NO FOR EACH TIME PERIOD)

	YES	NO	
A. TIME AT HOME FOLLOWING TRANSPLANT	01	02	41 42
B. ONE YEAR PRIOR TO TRANSPLANT	01	02	43 44

32. Did the recipient's health keep him/her from working at a job, doing work around the house, or going to school?

(CIRCLE YES OR NO FOR EACH TIME PERIOD)

	YES	NO	
A. TIME AT HOME FOLLOWING TRANSPLANT	01	02	45 46
B. ONE YEAR PRIOR TO TRANSPLANT	01	02	47 48

33. Did he/she need help with eating, dressing, bathing, or using the toilet because of health?

(CIRCLE YES OR NO FOR EACH TIME PERIOD)

	YES	NO
A. TIME AT HOME FOLLOWING TRANSPLANT	01	02
B. ONE YEAR PRIOR TO TRANSPLANT	01	02

34. Did the recipient's health limit him/her in any way from doing anything he/she wanted to do?

(CIRCLE YES OR NO FOR EACH TIME PERIOD)

	YES	NO
A. TIME AT HOME FOLLOWING TRANSPLANT	01	02
B. ONE YEAR PRIOR TO TRANSPLANT	01	02

35. At home following the transplant, did the recipient's health limit his/her ability to:

(CIRCLE YES OR NO FOR EACH TASK)

	YES	NO
A. REACH?	01	02
B. USE FINGERS TO GRASP OR HANDLE?	01	02
C. USE THEIR EYES FOR INSPECTION OF THINGS?	01	02
D. USE THEIR EYES FOR READING?	01	02
E. LIFT OR CARRY WEIGHTS UP TO 10 POUNDS?	01	02
F. LIFT OR CARRY WEIGHTS UP TO 25 POUNDS?	01	02
G. LIFT OR CARRY WEIGHTS UP TO 50 POUNDS?	01	02

4 0 2

FAMILY RELATIONS

We would like to get some idea of how a recipient's heart transplant affected his/her family life. The following questions concern the immediate family--that is, those with whom the recipient lived and/or had the most contact. If you do not consider yourself a member of the recipient's immediate family, please skip to the Overview Section, Q. 57.

36. All families are different—some are very close and others are not. At the time of the transplant, would you say the people in your immediate family were...

(CIRCLE ONE)

(Dup 1-6)

VERY CLOSE 01

PRETTY CLOSE 02

A LITTLE CLOSE, OR 03

NOT AT ALL CLOSE TO EACH OTHER?..... 04

7 8

37. How well were the people in your family getting along together at home at the time of the transplant?

(CIRCLE ONE)

VERY WELL 01

PRETTY WELL 02

A LITTLE WELL 03

NOT AT ALL WELL 04

9 10

38. How often were there arguments in your family around the time of the transplant?

(CIRCLE ONE)

ALMOST CONSTANTLY 01

OFTEN 02

ONCE IN A WHILE 03

NEVER 04

11 12

39. When a problem came up in the family during the transplant period, were the people in your immediate family...

(CIRCLE ONE)

VERY WILLING TO HELP OUT 01

SOMEWHAT WILLING 02

A LITTLE WILLING, OR 03

NOT AT ALL WILLING TO HELP OUT? 04

40. How often did your immediate family do things together around the time of the transplant?

(CIRCLE ONE)

VERY OFTEN 01

SOMETIMES 02

RARELY 03

NEVER 04

41. When you first found out that the recipient needed a heart transplant were you and your family...

(CIRCLE ONE)

EXTREMELY WORRIED 01

SOMEWHAT WORRIED 02

A LITTLE WORRIED, OR 03

NOT AT ALL WORRIED? 04

42. How would you characterize your family while the recipient was sick?

(CIRCLE ONE)

VERY TENSE AND NERVOUS 01

SOMEWHAT TENSE 02

A LITTLE TENSE 03

NOT AT ALL TENSE OR NERVOUS 04

43. How upset or disturbed do you feel your family was by the recipient's heart condition?

(CIRCLE ONE)

VERY UPSET 01

SOMEWHAT UPSET 02

A LITTLE UPSET 03

NOT AT ALL UPSET 04

21 22

44. Some heart transplant recipient's feel that their condition is very demanding of their family's time and energy, while others do not feel this way. Would you say the heart transplant took...

(CIRCLE ONE)

A LOT OF YOUR FAMILY'S TIME AND ENERGY 01

SOME OF THEIR TIME AND ENERGY, OR 02

A LITTLE OF THEIR TIME AND ENERGY? 03

23 24

45. How often did you feel that the heart transplant interfered with the family routine at home?

(CIRCLE ONE)

OFTEN 01

SOMETIMES 02

HARDLY EVER 03

NEVER 04

25 26

46. Sometimes families resent it when someone in the family can't carry out their normal activities or if they need extra help. Do you feel the recipient's heart condition caused any resentment in your family?

(CIRCLE ONE)

YES 01

NO 02

27 28

47. How much would you say the following people had to give up because of the heart transplant?

(CIRCLE ONE RESPONSE FOR EACH PERSON)

	VERY MUCH	SOME-WHAT	A LITTLE	NOT AT ALL	DOES NOT APPLY
A. YOURSELF	01	02	03	04	--
B. THE HEART TRANSPLANT RECIPIENT	01	02	03	04	--
C. THE CHILDREN IN THE FAMILY	01	02	03	04	05

48. How well do you think your family understood how the recipient felt about his/her heart transplant?

(CIRCLE ONE)

VERY WELL 01

SOMEWHAT WELL 02

NOT VERY WELL 03

49. How much did your family talk about the transplant?

(CIRCLE ONE)

VERY OFTEN 01

SOMETIMES 02

NEVER 03

50. In terms of other problems you and your family have faced, was the heart transplant...

(CIRCLE ONE)

A VERY GREAT PROBLEM 01

SOMEWHAT OF A PROBLEM 02

A SMALL PROBLEM, OR 03

NO PROBLEM AT ALL? 04

51. Do you think that the heart transplant in any way brought the family closer together or in any way drew the family apart?

(CIRCLE ONE)

BROUGHT CLOSER TOGETHER 01

DREW FAMILY APART 02

NEITHER 03

41 42

52. Do you know any other heart transplant recipients?

(CIRCLE ONE)

YES 01

NO 02

43 44

53. **IF YES,** in comparison to families of other heart transplant patients, do you feel your family was more helpful, less helpful, or about average?

(CIRCLE ONE)

MORE HELPFUL 01

LESS HELPFUL 02

ABOUT AVERAGE 03

I DON'T KNOW 04

45 46

IF YOU WERE THE SPOUSE OF THE RECIPIENT, ANSWER QUESTIONS 54-56; OTHERWISE GO TO THE OVERVIEW SECTION, Q. 57.

54. How long were you married to the recipient?

_____ YEARS

47 48

55. Do you think that the heart transplant placed a strain on your marriage?

(CIRCLE ONE)

YES 01

NO 02

49 50

56. How did the heart transplant affect your relationship with your spouse? Did you feel...

(CIRCLE ONE)

CLOSER 01

ABOUT THE SAME, OR 02

NOT AS CLOSE? 03

OVERVIEW

57. Because of the recipient's heart condition, do you think he/she needed...

(CIRCLE ONE)

A LOT OF EXTRA HELP TO GET THINGS DONE 01

SOME EXTRA HELP TO GET THINGS DONE 02

A LITTLE EXTRA HELP, OR 03

NO MORE HELP THAN ANY HEALTHY PERSON? 04

58. During the time the recipient was sick, do you feel they...

(CIRCLE ONE)

WERE MORE DEPENDENT ON OTHERS FOR HELP THAN THEY WANTED TO BE, OR 01

THAT THEY WANTED TO HAVE SOMEONE THEY COULD HAVE DEPENDED ON MORE, OR 02

NEITHER? ..... 03 **(GO TO Q. 60)**

59. How much of a problem was their dependence upon others after the heart transplant?

(CIRCLE ONE)

A GREAT PROBLEM 01

SOMEWHAT OF A PROBLEM 02

A SMALL PROBLEM 03

NO PROBLEM 04

57 58

60. Was the time after the transplant...

(CIRCLE ONE)

ABOUT WHAT YOU EXPECTED 01

WORSE THAN YOU EXPECTED, OR 02

BETTER THAN YOU EXPECTED? 03

59 60

61. Thinking back over the time since the recipient received the heart transplant, how often have you felt that it was a mistake?

(CIRCLE ONE)

NEVER 01

ALMOST NEVER 02

SOMETIMES 03

VERY OFTEN 04

ALWAYS 05

61 62

62. In general, do you feel that the recipient was well informed by doctors and transplant center staff **BEFORE** the operation about the transplant procedure and recovery?

(CIRCLE ONE)

YES 01

NO 02

63 64

63. Do you think the information on transplant costs the recipient received **PRIOR** to the transplant was accurate?

(CIRCLE ONE)

YES 01

NO 02

EMPLOYMENT

Now we would like to ask you a few questions about your work activity around the time of the transplant.

64. What was your employment status the year following the recipient's heart transplant?

(CIRCLE ONE)

EMPLOYED FULL-TIME 01

EMPLOYED PART-TIME 02

EMPLOYED BUT TEMPORARILY LAID OFF 03

UNEMPLOYED, LOOKING FOR WORK 04

UNEMPLOYED, NOT LOOKING FOR WORK .. 05

UNABLE TO WORK BECAUSE OF HEALTH (DISABLED) 06

HOMEMAKER 07

STUDENT (FULL-TIME) 08

RETIRED 09

OTHER (SPECIFY) _____ 10

4 0 3

65. Which of the following best describes your work activity **PRIOR** to the heart transplant?

(CIRCLE ONE)

(Dup 1-6)

EMPLOYED FULL-TIME 01

EMPLOYED PART-TIME 02

EMPLOYED BUT TEMPORARILY LAID OFF 03

UNEMPLOYED, LOOKING FOR WORK 04

UNEMPLOYED, NOT LOOKING FOR WORK .. 05

UNABLE TO WORK BECAUSE OF HEALTH (DISABLED) 06

HOMEMAKER 07

STUDENT (FULL-TIME) 08

RETIRED 09

OTHER (SPECIFY) _____ 10

7 8

66. **IF** there was a change in your employment status **AFTER** the recipient's heart transplant, was the change directly related to the transplant?

(CIRCLE ONE)

YES 01

NO 02

NO CHANGE 03

9 10

We would also like to know how the recipient's health affected his/her work activities.

Questions 67-71 refer only to the period of time **FOLLOWING THE HEART TRANSPLANT.**

67. Did the recipient's health keep him/her from working on a job for pay **AFTER** he/she received the heart transplant?

(CIRCLE ONE)

YES 01

NO 02

68. Was he/she limited in the **KIND** of work for pay he/she could do because of health?

(CIRCLE ONE)

YES 01

NO 02

69. Was he/she limited in the **AMOUNT** of work for pay he/she could do because of health?

(CIRCLE ONE)

YES 01

NO 02

70. Was he/she able to work for pay full-time, part-time, or not at all?

(CIRCLE ONE)

FULL-TIME 01

PART-TIME 02

NOT AT ALL ..... 03 **(GO TO Q.72)**

71. Was the recipient able to work for pay regularly or could he/she work only occasionally or irregularly?

(CIRCLE ONE)

REGULARLY 01

OCCASIONALLY OR IRREGULARLY 02

19 20

72. What was the recipient's work activity or employment status **AFTER** he/she received the heart transplant?

(CIRCLE ONE)

EMPLOYED FULL-TIME 01

EMPLOYED PART-TIME 02

EMPLOYED BUT TEMPORARILY LAID OFF 03

UNEMPLOYED, LOOKING FOR WORK 04

UNEMPLOYED, NOT LOOKING FOR WORK .. 05

UNABLE TO WORK BECAUSE OF HEALTH (DISABLED) 06

HOMEMAKER 07

STUDENT (FULL-TIME) 08

RETIRED 09

OTHER (SPECIFY) _____ 10

21 22

73. What was the recipient's work activity or employment status during the year **PRIOR** to the heart transplant?

(CIRCLE ONE)

EMPLOYED FULL-TIME 01

EMPLOYED PART-TIME 02

EMPLOYED BUT TEMPORARILY LAID OFF 03

UNEMPLOYED, LOOKING FOR WORK 04

UNEMPLOYED, NOT LOOKING FOR WORK .. 05

UNABLE TO WORK BECAUSE OF HEALTH (DISABLED) 06

HOMEMAKER 07

STUDENT (FULL-TIME) 08

RETIRED 09

OTHER (SPECIFY) _____ 10

WORK HISTORY

74. We are also interested in the recipient's work history; that is, the jobs he/she had, the kind of work done, when the job began and ended, as well as the rate of pay. PLEASE FILL IN THE TABLE ON THE FOLLOWING PAGE, BEGINNING WITH THE JOB THE RECIPIENT HAD **FIVE YEARS PRIOR** TO HIS/HER TRANSPLANT AND **ENDING WITH HIS/HER LAST JOB.**

Below, each of these items is described to help you understand what we are looking for. We realize that you may no longer remember or have access to all details of the recipient's employment, but please complete the table as best you can.

A. **OCCUPATION** - What kind of work did the recipient do? For example, was he/she an electrical engineer, a typist, school teacher, plumber, or what?

B. **KIND OF BUSINESS** - What kind of business or industry did the recipient work for? For example, did he/she work for a TV and radio manufacturer, a public or private school system, a retail shoe store, farm, or what?

C. **SELF-EMPLOYED** - Was the recipient self-employed or did he/she work for someone else?

D. **DATE RECIPIENT BEGAN JOB** - Please indicate the month and year the recipient began each job; for example, November, 1978.

E. **DATE JOB ENDED** - Please indicate the month and year each job ended; for example, October, 1980.

F. **REASON JOB ENDED** - Please note whether or not the reason the recipient quit or left each job was health-related.

G. **RATE OF PAY** - Here we are interested in how much the recipient earned or was paid per year before taxes on each job. Be sure to note whether the dollar amount was HOURLY, WEEKLY, MONTHLY, OR YEARLY. If the recipient worked at one job for several years, please indicate his/her final salary.

H. **HOURS WORKED** - How many hours per week did he/she usually work at each job? Note the number of hours the recipient was actually on the job each week.

I. **WEEKS WORKED** - How many weeks per year did the recipient work at each job? If he/she did not work an entire year at a given job, indicate how many weeks per year he/she would have worked had he/she stayed on the job.

WORK HISTORY

(COMPLETE ACCORDING TO THE INSTRUCTIONS ON THE PRECEDING PAGE)

	A	B	C	D	E	F	G	H	I
	OCCUPATION	KIND OF BUSINESS	SELF-EMPLOYED YES NO	DATE RECIPIENT BEGAN JOB MO YR	DATE JOB ENDED MO YR	REASON JOB ENDED HE AE HER RELATED OTHER	RATE OF PAY	NO HOURS WORKED PER WEEK	NO WEEKS WORKED PER YEAR
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									
11									
12									
13									
14									
15									

75. At the time of the heart transplant, was the recipient receiving any of the following? For each "YES" please list approximately how much he/she received from each benefit per month.

(CIRCLE ONE FOR EACH BENEFIT— FOR EACH YES, LIST AMOUNT)

	YES	NO	DOLLARS	
A. SOCIAL SECURITY RETIREMENT OR DISABILITY BENEFITS (GREEN CHECK) ..	01	02	$ _____	25 — — — 28
B. SUPPLEMENTAL SECURITY INCOME (SSI) BENEFITS (GOLD CHECK)	01	02	$ _____	— — — —
C. RAILROAD RETIREMENT BENEFITS	01	02	$ _____	33 — — — 36
D. VETERANS ADMINISTRATION BENEFITS	01	02	$ _____	— — — —
E. UNEMPLOYMENT COMPENSATION	01	02	$ _____	41 — — — 44
F. WORKMEN'S COMPENSATION	01	02	$ _____	— — — —
G. "AID TO FAMILIES WITH DEPENDENT CHILDREN" (AFDC) ASSISTANCE	01	02	$ _____	49 — — — 52
H. PUBLIC WELFARE OR ASSISTANCE	01	02	$ _____	— — — —
I. CIVIL SERVICE BENEFITS	01	02	$ _____	57 — — — 60
J. UNION OR EMPLOYER DISABILITY BENEFITS	01	02	$ _____	— — — —
K. UNION OR EMPLOYER RETIREMENT OR PENSION BENEFITS	01	02	$ _____	— — — —
L. ANY OTHER BENEFITS (SPECIFY) _____	01	02	$ _____	69 — — — 72

4 0 4
78 — 80

76. Did the recipient ever receive any of the following rehabilitation services after he/she became a heart transplant **candidate**?

(CIRCLE YES OR NO FOR EACH SERVICE)

(Dup 1-6)

	YES	NO
A. COUNSELING AND GUIDANCE	01	02
B. PHYSICAL THERAPY	01	02
C. JOB TRAINING	01	02
D. JOB PLACEMENT	01	02
E. VOCATIONAL OR BUSINESS SCHOOL TRAINING	01	02
F. COLLEGE OR UNIVERSITY EDUCATION	01	02
G. PSYCHOTHERAPY	01	02
H. SPECIAL DEVICES (e.g. BRACE, ARTIFICIAL LIMB)	01	02
I. CANE TRAINING FOR THE BLIND	01	02
J. TRAINING FOR PERSONAL CARE AND/OR LEISURE TIME ACTIVITIES	01	02

FINANCIAL IMPACT

77. If the recipient took up lodging near the center while awaiting transplantation, what arrangements were made for his/her permanent residence?

(CIRCLE ONE)

SOLD HOME 01

RENTED OUT HOME OR APARTMENT 02

LEFT OCCUPIED BY OTHER FAMILY OR FRIENDS 03

LEFT UNOCCUPIED UNTIL RETURN 04

OTHER (SPECIFY) _____ 05

DOES NOT APPLY 06

78. Has it been necessary for you to do any of the following to help pay for the recipient's transplant costs?

(CIRCLE YES OR NO FOR EACH ITEM)

	YES	NO	
A. BEGIN WORKING/RETURN TO WORK	01	02	29 30
B. GET A BETTER PAYING JOB	01	02	31 32
C. INCREASE NUMBER OF WORKING HOURS	01	02	33 34
D. BORROW MONEY FROM FRIENDS OR RELATIVES	01	02	35 36
E. MORTGAGE HOME OR OBTAIN A BANK LOAN	01	02	37 38
F. MOVE TO A LESS EXPENSIVE RESIDENCE	01	02	39 40

79. Are you currently paying medical bills and/or other debts associated with the recipient's heart transplant?

(CIRCLE ONE)

YES 01

NO ..... 02 — 41 42

80. A. **IF YES,** how much longer do you think it will take to pay these debts?

_____ YEARS — 43 44

B. **IF NO,** how long did it take you to pay these debts?

_____ YEARS — 45 46

81. Now we would like you to answer a few questions to get a better picture of your current financial situation. Approximately what was your total family income from all sources in 1982? Please include wages, salary, tips, commissions, and net income from own business, professional practice, partnership or farm, dividends, interest, annuities, rents, pension and disability benefits, social security, welfare payments and gifts.

(CIRCLE ONE)

LESS THAN $3,000	01
$ 3,000 - $ 3,999	02
$ 4,000 - $ 4,999	03
$ 5,000 - $ 5,999	04
$ 6,000 - $ 7,499	05
$ 7,500 - $ 9,999	06
$10,000 - $11,999	07
$12,000 - $14,999	08
$15,000 - $19,999	09
$20,000 - $24,999	10
$25,000 - $29,999	11
$30,000 - $39,999	12
$40,000 - $49,999	13
$50,000 OR MORE	14

82. Finally, we would like to get a very rough idea of your general financial situation by comparing your assets with any debts that you may have. To do this, first estimate the amount of money that you would have if you were to sell your house, cars and other personal property and pay off all mortgages, car loans and other debts. Next, add to this any money that you have in checking and savings accounts, credit unions, stocks, bonds and mutual funds. Roughly how much do you think that you would have?

(CIRCLE ONE)

LESS THAN $10,000	01
$ 10,000 - $ 24,999	02
$ 25,000 - $ 49,999	03
$ 50,000 - $ 99,999	04
$100,000 - $199,999	05
$200,000 or MORE	06

49 50

4 0 5
78 80

CONCLUSION OF THE QUESTIONNAIRE

We at the Battelle Human Affairs Research Centers very much appreciate the time and effort you have put into this questionnaire. The information you have provided is essential to meeting the objectives of the National Heart Transplantation Study. If you have any comments about this questionnaire, please record them on the following page. Also, if you would like to have a brief summary of the results of the study, which will be available by the end of the year, please fill out the enclosed form which will be filed separately from the questionnaire.

INSTRUCTIONS FOR RETURNING STUDY MATERIALS:

In order to keep your name separate from the questionnaire, we have provided two pre-addressed envelopes. You do **not** have to place postage on these envelopes.

- THE LARGER MANILA ENVELOPE SHOULD CONTAIN **ONLY** THE QUESTIONNAIRE.
- THE SMALLER MANILA ENVELOPE SHOULD CONTAIN THE FOLLOWING:
    - 1 White copy of the General Consent Form
    - 1 Yellow copy of the General Consent Form
    - 1 White copy of the Authorization For Review of Medical Records and Hospital Billing Information
    - 1 Yellow copy of the Authorization For Review of Medical Records and Hospital Billing Information
    - 1 Request for a summary of the study (optional).

Remember to keep the pink copies of the General Consent Form and the Authorization for Review of Medical Records and Hospital Billing Information for your own records.

In closing, if you should have any questions whatsoever, please do not hesitate to make a collect call to Dr. Roger W. Evans' office at (206) 525-3130, extension 457. Once again, we are very grateful for your participation in this very important study.

COMMENTS

Yes, I would like to receive a summary of the National Heart Transplantation Study.

Name _____

Address _____

City _____ State _____ Zip Code _____

APPENDIX 7-C

PATIENT ROSTER FORM

TRANSPLANT CENTER NAME: _____

HEART TRANSPLANT PATIENT ROSTER

This list should contain the names of all patients transplanted at your center since your transplant program began through June 30, 1983. Patients should be in chronological order according to the date of their most recent transplant. Use as many pages as necessary to list all your patients.

PATIENT NAME (LAST, FIRST)	MONTH AND YEAR OF LAST TRANSPLANT (MO. YEAR)	CURRENT PATIENT AGE (YEARS)	WAS THE PATIENT DISCHARGED FROM THE HOSPITAL ALIVE? (Y/N)	HOW MANY TRANSPLANTS HAS THE PATIENT HAD? (1, 2, 3)	IS THE PATIENT CURRENTLY LIVING OR DECEASED? (L/D)	IF PATIENT IS DECEASED, RECORD DATE OF DEATH (MO. YEAR)

APPENDIX 7-D

GENERAL INFORMATION FORM FOR FAMILY OR HOUSEHOLD MEMBER RESPONDENTS OF LIVING TRANSPLANT RECIPIENTS

TRANSPLANT CENTER NAME: _____

TODAY'S DATE: _____

GENERAL INFORMATION FORM FOR LIVING HEART TRANSPLANT RECIPIENTS
AND THEIR FAMILY OR HOUSEHOLD MEMBER RESPONDENTS

1. What is this patient's name?

_____
FIRST LAST

2. What is this patient's six digit study identification number?

___/___/___/___/___/___

3. Has this patient been asked to participate in the National Heart Transplantation Study?

(CIRCLE ONE)

YES..... 01

NO 02

4. Has this patient agreed to participate in the study?

(CIRCLE ONE)

YES, THE PATIENT WANTS TO PARTICIPATE ..... 01 CONTINUE

NO, THE PATIENT DOES NOT WANT TO PARTICIPATE..... 02 STOP

5. What is this patient's current mailing address?

STREET _____

APT. NO. _____

CITY, STATE _____, _____

ZIP CODE _____

6. What is this patient's current telephone number?

(_____)_____
AREA CODE NUMBER

☐ CHECK THIS BOX IF THE PATIENT HAS NO PHONE

7. If the patient does not have a telephone, is there a telephone number at which he/she may receive messages?

(_____)_____
AREA CODE NUMBER

8. Has a family or household member been identified who has agreed to participate in this study?

(CIRCLE ONE)

YES 01

NO ..... 02 (KEEP TRYING)

9. What is the name of a family or household member to whom a questionnaire can be mailed?

_____
FIRST LAST

10. What is this person's relationship to the patient (e.g., spouse, brother, sister, mother, father, aunt, uncle, etc.)?

_____
SPECIFY

11. If different from the patient's, what is this person's current mailing address?

STREET _____

APT. NO. _____

CITY, STATE _____,_____

ZIP CODE _____

12. If different from the patient's, what is this person's current telephone number?

(_____)_____
AREA CODE NUMBER

☐ CHECK THIS BOX IF THE PERSON HAS NO PHONE

13. If the person does not have a telephone, is there a phone number at which he/she may receive messages?

(_____)_____
AREA CODE NUMBER

APPENDIX 7-E

GENERAL INFORMATION FORM FOR FAMILY OR HOUSEHOLD RESPONDENTS OF DECEASED RECIPIENTS

TRANSPLANT CENTER NAME: _____

TODAY'S DATE: _____

GENERAL INFORMATION FORM FOR FAMILY OR HOUSEHOLD MEMBERS OF
DECEASED HEART TRANSPLANT RECIPIENTS

1. What is the patient's name for whom this person will be asked to provide information?

_____
FIRST LAST

2. What is this patient's six digit study identification number?

___/___/___/___/___/___

3. What is the person's name who will respond on behalf of this patient?

_____
FIRST LAST

4. Has this person agreed to participate in the study?

(CIRCLE ONE)

YES, THE PATIENT WANTS TO PARTICIPATE ..... 01 CONTINUE

NO, THE PATIENT DOES NOT WANT TO PARTICIPATE..... 02 → ATTEMPT TO LOCATE ANOTHER PERSON AND FILL OUT ANOTHER FORM

5. What is this person's relationship to the patient (e.g., spouse, brother, sister, mother, father, aunt, uncle, etc.)?

_____
SPECIFY

6. What is this person's current mailing address?

STREET _____

APT. NO. _____

CITY, STATE _____, _____

ZIP CODE _____

7. What is this person's current telephone number?

(_____)_____
AREA CODE NUMBER

☐ CHECK THIS BOX IF THE PERSON HAS NO PHONE

8. If the person does not have a telephone, is there a phone number at which he/she may receive messages?

(_____)_____
AREA CODE NUMBER

APPENDIX 7-F

CONTACT FORMS

NATIONAL HEART TRANSPLANTATION STUDY
FAMILY OR HOUSEHOLD MEMBER-NEXT-OF-KIN - LIVING

NAME: _____ I.D.# _____

CITY/STATE: _____

PHONE: (___) _____

TRANSPLANT CENTER: _____

STAFF MEMBER CONTACT: _____

DATE RESPONDENT CONTACTED: _____

	DATE	INITIALS
SURVEY PACKET MAILED		
INITIAL FOLLOW-UP CALL		
SURVEY MATERIALS RETURNED		

ADDITIONAL COMMUNICATION

TO

FROM

NATIONAL HEART TRANSPLANTATION STUDY
FAMILY OR HOUSEHOLD MEMBER-NEXT-OF-KIN - DECEASED

NAME:_____ I.D.#_____

CITY/STATE:_____

PHONE: ( )_____

TRANSPLANT CENTER:_____

STAFF MEMBER CONTACT: _____

DATE RESPONDENT CONTACTED: _____

	DATE	INITIALS
SURVEY PACKET MAILED		
INITIAL FOLLOW-UP CALL		
SURVEY MATERIALS RETURNED		

ADDITIONAL COMMUNICATION

TO

FROM

APPENDIX 7-G

GENERAL CONSENT FORM

NATIONAL HEART TRANSPLANTATION STUDY

GENERAL CONSENT FORM
FAMILY OR HOUSEHOLD MEMBER

You are being asked to participate in the first major study of heart transplant recipients and their family or household members. This study, conducted by the Battelle Human Affairs Research Centers in Seattle, Washington, is concerned not only with the financial aspects, but with all aspects of heart transplantation including how well recipients and their families are doing at this time. We are also interested in any problems you may have had or are currently having. For clarity, we have divided the study into several major research components. These components include: (1) an estimate of the number of people requiring heart transplants in the United States; (2) the demonstrated value of heart transplantation as a medical procedure; (3) the availability of donor hearts; (4) the cost of performing a heart transplant and the routine medical management that occurs thereafter; (5) the quality of life enjoyed by heart transplant recipients both before and after their heart transplant; and (6) various legal and ethical dilemmas that surround heart transplantation as a procedure not suitable for everyone.

Six heart transplant centers have been selected by the Federal government to participate in the study. They are: (1) University of Arizona (Tucson, AZ); (2) Columbia Presbyterian Hospital and Medical Center (New York, NY); (3) Medical College of Virginia (Richmond, VA); (4) University of Minnesota (Minneapolis, MN); (5) University of Pittsburgh (Pittsburgh, PA); and (6) Stanford University Medical Center (Stanford, CA). As participants in the study, each transplant center agreed to contact their heart transplant recipients and the recipients' families for purposes of cooperating with us in the study. The transplant center where your family or household member received his or her transplant informed us that you were interested in the study.

If you agree to participate in the National Heart Transplantation Study family or household member survey, you are asked to fill out the questionnaire which has been sent to you with this consent form. The study is designed to give us information about the health, family and social life, financial situation, overall quality of life, and experience with rehabilitation and social service agencies of the transplant recipient.

Your participation in this study is purely voluntary. You may refuse to fill out the questionnaire altogether, or, if you decide to participate, you may leave any question or item unanswered.

While we would also like to obtain some information contained in the medical and billing records kept by the transplant center, your signature on this consent form gives us permission *only* to use the information you supply by your answers to the questionnaire; it does *not* give us permission to see any medical records or hospital billing information. We will review those items only if we have permission from the appropriate person as indicated on the "Authorization for Review of Medical Records and Hospital Billing Information" form. If you, as the authorized signer, give us permission to see the medical records, only information about the heart transplant and treatment will be studied. In addition, you may restrict our access further by indicating on the authorization form that you wish us to rexamine the record of treatment of the heart transplant recipient only between certain dates, or that you do not wish to disclose to us information in the medical records about any condition or subject matter.

All information that we receive based on your answers to the questionnaire, the medical records, and hospital billing records is kept *strictly confidential.* We will give no one, including the government or the doctors involved in the treatment of the transplant recipient, the information you provide to us that would personally identify you or the transplant recipient. Neither your name nor that of the recipient will appear on the questionnaire. Once the information has been collected, it will no longer be associated with either you or the recipient.

If you have any questions about how we intend to use the information you provide, or about the meaning of any item of the questionnaire, you may make a collect call to the National Heart Transplantation Study project director, Dr. Roger W. Evans, at (206) 525-3130. We hope that you will agree to participate in this important study; the results of this survey will provide a better understanding of the status of people who have received heart transplants.

With the above assurances that my rights will be protected, I now give my consent to participate in this study.

Name: _____
(Please Print)

_____
(Signature)

Relationship to the
Transplant Recipient: _____

Date: _____

OMB 0938-0189
(Exp. 12/83)

APPENDIX 7-H

CONSENT FORM AUTHORIZING THE REVIEW OF MEDICAL RECORDS AND HOSPITAL BILLING INFORMATION

NATIONAL HEART TRANSPLANTATION STUDY

AUTHORIZATION FOR REVIEW OF MEDICAL RECORDS AND HOSPITAL BILLING INFORMATION

Name: _____
(Please Print)

Relationship to Heart Transplant Recipient: _____

Name of Heart Transplant Recipient: _____
(Please Print)

Place Transplant Performed: _____

Date Transplant Performed: _____

This form authorizes a data abstractor for the National Heart Transplantation Study being conducted by the Battelle Human Affairs Research Centers in Seattle, Washington, to study the hospital billing records and all or part of the medical records that apply to the treatment of the heart disease, the heart transplant, and associated care of the named heart transplant recipient as indicated below. (Please mark the appropriate responses.)

Authorization to Review Medical Records

_____ I give my permission to review and, if necessary, to make a copy of the *complete record* of the history of the heart disease and treatment of the named heart transplant recipient.

_____ I wish to restrict access to the medical records as indicated below:

_____

_____

_____

Authorization to Review Hospital Billing Records

_____ I give my permission to review and, if necessary, make a copy of the hospital billing records pertaining to the treatment for heart disease, the transplant, and any associated care of the named heart transplant recipient.

Signature: _____ Date _____

This authorization must be signed by a family or household member of the heart transplant recipient and will be valid for one year from date, unless otherwise directed by the family or household member.

OMB 0938-0189
(Exp. 12/83)

APPENDIX 7-I

REQUEST FORM FOR SUMMARY OF STUDY RESULTS

Yes, I would like to receive a summary of the National Heart Transplantation Study.

Name _____

Address _____

City _____ State _____ Zip Code _____

APPENDIX 7-J

COVER LETTER
FAMILY OR HOUSEHOLD MEMBER OF
LIVING HEART TRANSPLANT RECIPIENTS

Battelle
Human Affairs Research Centers
4000 N.E. 41st Street
P.O. Box C-5395
Seattle, Washington 98105
Telephone: (206) 525-3130
Cable: HARCSEA

October 28, 1983

Dear :

As I'm sure you already know, we at the Battelle Human Affairs Research Centers are currently conducting a nationwide study of heart transplantation. As part of this study, and five other heart transplant programs in the United States are helping us to collect important information on heart transplant recipients and their families. As a family member or close friend of a heart transplant recipient, we understand that you have been contacted by someone from regarding your participation in the study.

Enclosed is a copy of the Family or Household Member Questionnaire (Form A) which we would like you to complete. Please read the introduction to the questionnaire before you begin. Most of the questions focus on how the heart transplant has affected you and other individuals close to the transplant recipient. Since we have already asked your to answer many of these same questions, we would like you to complete the questionnaire without consulting .

Within the next week or so, a survey assistant from Battelle will be calling you to answer any questions that you may have regarding the survey. If possible, it would be helpful if you would complete as much of the questionnaire as you can before you receive the call.

Thank you very much for your help in this important study.

With my kindest regards,

Roger W. Evans, Ph.D.
Project Director
National Heart Transplantation Study

RWE:mg
Enclosure

APPENDIX 7-K

COVER LETTER
FAMILY OR HOUSEHOLD MEMBER OF
DECEASED HEART TRANSPLANT RECIPIENTS

Battelle
Human Affairs Research Centers
4000 N.E. 41st Street
P.O. Box C-5395
Seattle, Washington 98105
Telephone: (206) 525-3130
Cable: HARCSEA

December 1, 1983

Dear :

As you probably know, we at the Battelle Human Affairs Research Centers are currently conducting a nationwide study of heart transplantation. As part of this study, and five other heart transplant programs in the United States are helping us to collect important information on heart transplant recipients and their families. This includes both living heart transplant recipients and their families, as well as family members of deceased transplant recipients. We understand that you have been contacted by someone from and that you have indicated a willingness to participate in the study.

Enclosed is a copy of the Family or Household Member Questionnaire (Form B) which we would like you to complete. Please read the introduction to the questionnaire before you begin. The questions focus not only on how the heart transplant affected the recipient, but also on how the transplant affected yourself and other individuals close to the transplant recipient. Some of the questions may be difficult for you to answer. However, we feel that only a close friend or relative of a deceased transplant recipient, such as yourself, will be able to provide important information about heart transplantation that we can not get from other sources.

Within the next week or so, a survey assistant from Battelle will be calling you to answer any questions that you may have regarding the survey. If possible, it would be helpful if you would complete as much of the questionnaire as you can before you receive the call.

Thank you very much for your help in this important study.

With my kindest regards,

Roger W. Evans, Ph.D.
Project Director
National Heart Transplantation Study

RWE:mg
Enclosures

CHAPTER 8

THE PARTICIPATING HEART TRANSPLANT PROGRAMS

Roger W. Evans, Ph.D.
Research Scientist
Health and Population Study Center
and
Julie Elworth, M.A.
Research Specialist
Social Change Study Center
Battelle Human Affairs Research Centers
4000 N.E. 41st Street
Seattle, Washington 98105

A. INTRODUCTION

As noted in Chapter 1 of this report, 6 of the 12 institutions that applied for funding under the National Heart Transplantation Study were eventually selected to participate in the study. These institutions are as follows: (1) the University of Arizona Health Sciences Center, (2) the Columbia Presbyterian Medical Center, (3) the Medical College of Virginia, (4) the University of Minnesota, (5) the University of Pittsburgh, and (6) Stanford University Medical Center. For purposes of this report, it is important to describe each of these institutions, even though there is considerable similarity across heart transplant programs. Most heart transplant programs in the United States and abroad have followed the lead of the Stanford program. Thus, considerable similarity is to be expected. Nonetheless, there are unique features associated with each of the programs that participated in the National Heart Transplantation Study and, to the extent possible, it is important to highlight these differences.

Unfortunately it was impossible for us to collate all the descriptive program data that we would have liked. All programs differed with respect to the availability of data on their programs. Some programs had very detailed protocols, while others had little written documentation available. The information contained in this chapter were provided by each of the participating centers. In some instances, members of the transplant teams have actually written the descriptions that appear. In others, we have had to consult available publications in an attempt to describe programs. In addition to describing each program historically, we have chosen to describe seven

aspects of each program. These aspects are as follows: (1) patient selection criteria, (2) transplant team members, (3) patient consent forms, (4) equipment required for heart transplantation, (5) number of heart transplants by year, (6) transplant protocol, and (7) persons who assisted with data collection for the National Heart Transplantation Study. In only a few instances has it been impossible for us to describe these seven aspects of each program (for example, if a program failed to provide the necessary information such as an equipment list). Nonetheless, the descriptions that follow are certainly adequate for shedding the necessary light on each of the participating programs. If further information should be desired, a member of the transplant team at each center should be contacted in hopes that they will be able to provide the needed information.

B. UNIVERSITY OF ARIZONA HEALTH SCIENCES CENTER

In July 1977, the University of Arizona Health Sciences Center began to plan for a cardiac transplantation program. Dr. Jack G. Copeland had just arrived from Stanford University and found the existing cardiac surgery program too small and inefficient to undertake cardiac transplantation. Therefore, initially his primary efforts were directed to establishing a strong clinical program. The progress made is shown in Table 8-1.

Prior to 1977, approximately 20 open heart surgical cases per year were done, therefore, several important institutional changes were implemented. An operating suite was established solely for cardiothoracic surgical procedures. Teams of operating room personnel and anesthesiologists who "specialized" in cardiac surgery were

Table 8-1
Cardiovascular Activity At The University of Arizona
Health Sciences Center

PROCEDURE	YEAR 1	YEAR 2	YEAR 3
Cardiopulmonary bypass cases	197	217	263
Cardiac catheterizations	411	518	548

organized. A cardiothoracic intensive care unit (5 beds), with associated telemetry unit (5 beds), coronary care unit (5 beds), and medical intensive care unit (5 beds), were identified as separate but adjacent units with a strong interchangeable staff. The surgical staff increased from one to three full-time cardiac surgeons with a strong interest in transplantation.

By mid-1978 the program was running smoothly, operative mortality statistics were comparable to any major center in the United States (coronary artery bypass 1.7%, aortic valve replacement 3%, mitral valve replacement 6%, tetralogy of Fallot 3%), and the Division of Cardiothoracic Surgery began to organize for cardiac transplantation. Several levels of organization proceeded simultaneously. The hospital administration was informed of the Division's intention to begin heart transplantation within one year. They responded positively, helping the Division particularly by establishing a policy to prevent any conflict of interest in the procurement of donors. Inservice teaching initially began with the operating room and intensive care personnel, and later included the immediate academic medical community, the medical and surgical communities of Tucson and Phoenix, and a few service organizations of laymen in Tucson. This stimulated the creation of protocols for nursing care of heart transplant patients and an operating room procedures manual. The nursing care protocol was based upon a protocol which has been in existence at Stanford since the beginning of their cardiac transplantation program. Various Stanford protocols for recipient care immediately after transplantation and extending to chronic care following discharge were revised. Other

departments and divisions were most helpful during this planning phase. Neurology reviewed the literature on brain death and wrote a definition including the procedure for declaration of brain death which has been incorporated into the protocol. The immunology laboratory set up the T-lymphocyte assay which is a vital part of the current diagnostic approach to rejection. Cardiology was extremely cooperative in the evaluation of patients who might benefit from heart transplantation and in equipping the catheterization laboratory with endomyocardial bioptomes.

In November 1978, a cardiologist from the community referred a patient for transplantation. After evaluation he seemed to be a reasonable candidate and the intent to proceed with cardiac transplantation was made known. This announcement stimulated some concern from the Department of Anesthesia and further organizational meetings outlined procedures to be followed which met with the approval of all involved. The intent to proceeded with heart transplantation also led to some modifications of the ventilation systems in one room in the cardiothoracic intensive care unit and one in the telemetry unit which were henceforth designated as the "transplant rooms." The simple modifications in the air-handling system increased the airflow volume into each of the rooms so that a slightly positive pressure would result. Medical-grade air filters were also installed.

A suitable donor was found and the first heart transplant was completed on March 27, 1979. The recipient was 49 years old at the time of transplant. Since that time the University of Arizona program has performed 42 heart transplants.

1. PATIENT SELECTION CRITERIA

As at most heart transplant programs, the selection criteria for heart transplant recipients at Arizona are very stringent. These criteria take into consideration the current status of heart transplantation and also are intended to maximize the outcomes that patients experience. At Arizona, patients are included as potential cardiac transplant recipients if they meet the following criteria:

- have a reasonable chance of long-term survival
- all other reasonable medical and surgical alternatives have been tried
- are expected to survive without the transplant less than 6-12 months

Patients are generally excluded if they exhibit any of the following contraindications:

- pulmonary vascular resistance elevation greater than eight Wood units
- ongoing diseases of any organ (brain, kidney, liver) independent of cardiac failure
- recent pulmonary infarction
- active peptic ulcer disease
- significant peripheral or cerebrovascular disease
- insulin-dependent diabetes mellitus
- drug or alcohol addiction
- absence of sufficient ego strength or adequate psychological support from immediate family and friends

2. TRANSPLANT TEAM MEMBERS

The cardiac transplant team at Arizona includes staff members from both the University and the Veteran's Administration Medical Center. The cardiothoracic team is made up of two cardiothoracic surgeons, two transplant coordinators, three perfusionists, and two research scientists. Specific individuals who are associated with the transplant program include the following:

NAME	POSITION	DEPARTMENT
Jack G. Copeland, M.D.	Associate Professor Surgery Department, Chief, Division of Cardiovascular and Thoracic Surgery	Surgery
Robert Emery, M.D.	Assistant Professor, Surgery Department Division of Cardio-- vascular and Thoracic Surgery	Surgery
Jan Copeland, R.N.	Transplant Coordinator	Division of Cardiovascular and Thoracic Surgery
Mary Jean McAleer, R.N.	Transplant Coordinator	Division of Cardiovascular and Thoracic Surgery
Douglas F. Larson, Ph.D. C.C.P.	Research Associate Professor and Perfusionist	Division of Cardiovascular and Thoracic Surgery
Raymond Ramirez, C.C.P.	Chief Perfusionist	Division of Cardiovascular and Thoracic Surgery
Tina Mazur, C.C.P.	Perfusionist	Division of Cardiovascular and Thoracic Surgery

Frank I. Marcus, M.D.	Professor	Division of Cardiology
Gordon A. Ewy, M.D.	Professor and Chief Cardiology	Division of Cardiology
Paul E. Fenster, M.D.	Assistant Professor	Division of Cardiology
Steven Goldman, M.D.	Co-Director,	VA Medical Center Cardiology Section
Colin Banford, M.D.	Acting Head	Neurology
William A. Sibley, M.D.	Professor	Neurology
Steward Snyder, M.D.	Associate Professor	Neurosurgery
Charles F. Zukoski, M.D.	Professor of Surgery, AHSC and Assistant Chief, Surgical Services	Surgery (Renal Transplantation) VA Medical Center
David A. Ogden, M.D.	Professor of Medicine	Medicine (Renal Transplantation)
C. Don Beavers	Renal Disease Project	VA Medical Center Transplant Coordinator
Charles W. Otto, M.D.	Assistant Professor	Anesthesiology
Jerry M. Calkins, M.D.	Assistant Professor Assistant Professor	Anesthesiology Biomedical Electrical Engineering
Randall C. Cork, M.D.	Assistant Professor	Anesthesiology
Jack M. Layton, M.D.	Professor and Head	Pathology
John R. Davis, M.D.	Professor	Pathology
Samuel H. Paplanus, M.D.	Professor	Pathology
Richard C. Froede, M.D.	Associate Professor	Pathology
Raymond B. Nagle,M.D.,PhD	Associate Professor	Pathology

Richard E. Sobonya, M.D.	Associate Professor	Pathology
Jacob L. Pinnas, M.D.	Associate Professor	Internal Medicine (Immunology)
David O. Lucas, Ph.D.	Associate Professor	Microbiology (Immunology)
Douglas W. Huestis, M.D.	Professor of Pathology	Clinical Pathology
Mary J. Parker Hicks, M.D.	Assistant Professor of Pathology	Clinical Pathology
Stanton G. Axline, M.D.	Associate Professor Chief, Infectious Disease Section	Internal Medicine (Infectious Disease) at VA Medical Center
Kenneth J. Ryan, M.D.	Associate Professor	Pathology and Microbiology (Infectious Disease)
John N. Galgiani, M.D.	Assistant Professor, Chief, Infectious Disease Section	Infectious Disease Section, VA Medical Center
James Ito, M.D.	Assistant Professor	Infectious Disease Section, Dept. of Internal Medicine
Charles G. Ray, M.D.	Professor of Pediatrics	Clinical Virology and Serology Laboratory
Alfred W. Kaszniak, Ph.D	Assistant Professor	Division of Clinical Psychology
James Allendar, M.A.	Psychology Associate	Division of Clinical Psychology

Patty Lafferty, M.A.	Psychology Associate	Division of Clinical Psychology
Susan E. Newman, M.A.	Director of Social Services	
Nancy Miester, M.S.W.	Medical Social Worker	
Nancy P. Miniat, B.S.	Clinical Dietician	
Debbra Grella, B.S.	Clinical Dietician	
Robert O. Lesher, L.L.B. Lesher, Kimble, and Rucker, P.C.	Legal Counsel to the UAHSC	

3. PATIENT CONSENT FORMS

Patients undergoing cardiac transplantation are required to sign a consent form indicating that they are knowledgeable of the procedure they must undergo as treatment for end-stage cardiac disease. A copy of the patient consent form is attached herewith as Appendix 8-A.

4. EQUIPMENT

A detailed list of the equipment and supplies required for cardiac transplantation has been provided by the University of Arizona team. The complete list is reproduced below.

1	Airway, size 5
2	Albumen: Bottle 250cc
1	Alcohol Prep Pk100
1 box	Bandage - Plastic
5	Bandage: Gauze fine mesh 4x4 stretch
1 box	Betadine swabs
10 each	Catheter suction kit 14 FR 22 in
10 each	Cap for injection huer-lock
3	Cassette: IMED
3	Container specimen
4	Dressing - Petrolatum 3x9
1	Depressors - tongue adult
2	Electrode kit-wire connecting color coded
3	Electrode: Monitoring PreGel adult Pk
1	Graduate stainless steel

2	12/box	Gauze sponge 4x4
2		Gauze sponge 2x2
2		Gauze sponge (Tubs)
1	box	Gloves (Exam large singles)
5		Gloves Sterile 7
5		Gloves Sterile 6
5		Gloves Sterile 7-1/2
5		Gloves Sterile 8
2		Forcep: Hemostate Crile
2		Forcep: Tubing clamp
2		Filter - Blood micro
2		Filter Inline .22
1	btl	H_2O_2 4 oz.
1		Irrigsol SodChl 500ml
1		Irrigsol Sterile HCO 500ml
2		Hetastarch

ISOLATION CART

2		IV Start pak
3		IV set Buretrol 150cc
3		IV set admped 2n Line
2		IV set Blood adm Y. type
4		IV Sol D51.2 NaCl 500cc
1		IV Sol Sod Chl 0.9 250cc
9		Kit Bedside kit adult
1	btl	Labstix stripes
1	btl	Lotion (hand and body)
10		Lab Jelly Foil packs
1	pk	Cups: Medicine plastic graduated
2		Needle cath (Quick cath) 18g
2		Needle cath (Quick Cath) 20g
2		Needle cath (Quick Cath) 22g
1	box	Needle 18 - 1-1/2
1	box	Needle 20 - 1 inch
1	box	Needle 21 - 1-1/2 inch
1	box	Needle 22 - 1-1/2 inch
1	box	Needle 23 - 1 inch
1		Pacemaker
2	btls	Providone Iodine 2 ox bottles
1		Admit kit
2	pkgs	Restraints
1		Tape Adhesive Surg Dermicel 1 inch
1		Tape Adhesive Surg Dermicel 2 inch
1		Tape Adhesive Surg Microphore 1 inch
1		Tray - Irrig with catheter tip syringe
1		Tray subclavial dressing
1		Water - vial 30cc Bacteriostatic
10		Water Amp 10cc
2		Scissors sharp
1		Scissors wire
5		Swag (lemon/Glycerine)
5		Syringes Arterial Blood Gas
1	box	Syringes 3cc

1 box	Syringes 6cc
1 box	Syringes 12cc
10 only	Syringes 20cc
1 box	Syringes 60cc
10	NaCl amp 5 ml (injectable)
1	Suture removal kit
1	Thermometer oral
1	Thermometer rectal
1	Tube salem sump 16FR
2	Tube yankauer
1	Tubex
1	Urimeter for Specific gravity
	IV Pole - manafold - screwdriver
	Pen - for room
	Clean B/P cuff
	Blood bags (Pressure Black)
	Stethescope
1	Wall suction
2	Floor suctions
5	Blood tubes blue small
5	Blood tubes red small
5	Blood tubes Green small
5	Blood tubes green large
5	Blood tubes red large
5	Blood tubes purple large

KITCHEN

	Plastic basket (clean)
	Straws
	Drinking cups
	Ventilator with ambubag
	ET cuff manometer
	Garbage bags

CLEANING SUPPLIES (From housekeeping)

	Mop (not sponge)
	Bottle of cleaning solution
	Disposable wipes

DRUGS

2	Diazepam 10mgm syringe
2	Epinephrine 1:1000
20	Heparine Flushes (100u)
1	Metaraminol (aramine) 10mgm/ml
2	KCl
1	Bicarb (50mg)
2	Nido (2% 200mgm)
1	Isuprel 1:5000 (2mgm)
10 pkts	Povidone pint packets

5. NUMBER OF TRANSPLANTS

There has been a steady increase in the number of heart transplants performed at the University of Arizona. As shown in Table 8-2, four fewer procedures were performed in 1983 than in 1982. Overall, 42 transplants had been performed at the University of Arizona at the close of 1983.

6. TRANSPLANT PROTOCOL

The technique of orthotopic cardiac transplantation has changed little since its description by Lower and Shumway in 1960. The preoperative preparation includes placement of a central venous line in the left internal jugular vein; the right internal jugular vein, a route of entry for the endomyocardial bioptome after transplantation, remains undisturbed. Preoperative broad-spectrum antibiotics are administered before the initial incision. Anesthetic management must be gentle, avoiding cardiac depression. Sterile technique is followed in endotracheal tube placement. An arterial line and 1 or 2 peripheral intravenous lines are used. Foley catheters are avoided and suptapubicbladder catheterization is preferred as an aseptic technique of bladder drainage.

The operation proceeds as indicated. Cannulae for venous return are placed in the cavae via the right atrium. Total cardiopulmonary bypass occluding venous inflow to the heart with choker tapes constricting the cavae around the canulae provides a nearly bloodless field. After fibrillating the recipient heart and clamping the ascending aorta, the heart is removed. Some blood returns to the left atrium via bronchial artery collaterals. The donor heart is prepared for implantation and a control biopsy of right

Table 8-2
Number of Heart Transplants By Year At The
University of Arizona Health Sciences Center

YEAR	NUMBER OF PROCEDURES
1979	4
1980	6
1981	8
1982	14
1983	10

ventricular endocardium is taken. Anastomoses of the atrial cuffs, first left, then right, are completed with a continuous suturing technique. Cold (4C) saline is then flushed continuously through the left atrium and out the aorta for the dual purpose of removing air from the left heart and maintaining a low myocardial temperature. After completion of the end-to-end aortic anastomosis, cooling is discontinued, the aortic cross clamp is removed and, after a short period of coronary reperfusion, the heart is defibrillated. The end-to-end pulmonary arterial anastomosis is then completed. After 30 minutes of resuscitation of the beating donor heart, cardiopulmonary bypass is discontinued. Hemostasis of all suture lines is rechecked several times and fresh frozen plasma is administered to patients taking warfarin up to the time of operation. A temporary pacing wire is placed in the right atrium and exited from the chest under the right costal margin. The remainder of the procedure consists of routine chest tube placement and median sternotomy closure. A diluted drip of isoproterenol (4 Ug per milliliter at 1 Ug per minute) or dopamine (800 Ug per milliliter at 5 Ug per kilogram per minute) is started to augment the cardiac output.

Postoperatively, extubation is carried out in recipients as soon as they are awake and their cardiovascular status is stable. Chest tubes are removed when the volume of drainage decreases to less than 100 ml for 8 hours. Full reverse isolation is maintained for 1-3 weeks in the intensive care unit.

7. NATIONAL HEART TRANSPLANTATION STUDY DATA COLLECTION

The project team owes a great debt to several members of the cardiac transplant team at the University of Arizoma for collecting

the required data for the study. Data were abstracted from medical and hospital records as well as hospital financial records. The task was substantial. Those persons who were responsible for or assisted with data collection are as follows:

- Mary Jean McAleer, R.N.
- Jan Copeland, R.N. (on-site project coordinator)
- Jack G. Copeland, M.D. (on-site principal investigator)

C. COLUMBIA-PRESBYTERIAN MEDICAL CENTER

The Department of Surgery at Columbia-Presbyterian Medical Center in New York City began a program of heart transplantation under the direction of Dr. Keith Reemtsma in January, 1977. Since that time, the program has remained active and, as of the end of calendar year 1983, has performed 37 heart transplants. In 1983 alone, the team at Columbia performed 16 of these procedures. It is expected that the program, now under the direction of Dr. Eric Rose, will continue to expand.

1. PATIENT SELECTION CRITERIA

Patients who are considered as possible candidates for cardiac transplantation are thoroughly evaluated at Columbia-Presbyterian Medical Center (CPMD), although evaluation records, to the extent available, may also be forwarded by the patient's referring cardiologist. The following clinical studies and evaluation results are required to determine if a person is an acceptable candidate for cardiac transplantation:

a. Evaluation Studies.

- Referral by local physician with patient information to include:
  - A complete clinical summary
  - All X-rays, angiograms, and catheterization reports for review
  - A patient/family social service history
  - Dental records from the family dentist
- Admission to CPMC on the chest service for pretransplant assessment - under cardiology supervision
  - Complete history and physical examination.
  - Discussion with patient regarding feelings about transplantation.
  - Routine assessment: CBC, ESR, urinalysis, SMAC, blood type, thyroid function studies PEP, EKG, chest x-ray, Fe/TBC, arterial blood gases.
- Cardiac catheterization
  - hemodynamic study to measure pulmonary vascular resistance
  - study before and after vasodilator Rx
  - angiography as indicated
  - myocardial biopsy if indicated
- Electrophysiology evaluation, if indicated
  - Holter monitor
  - His bundle study - arrythmia susceptability study

Patients may have relative or absolute contraindications for heart transplantation. These contraindications are as follows:

- Relative contraindications
  - patients over 50 years of age
  - patients with other systemic disease, e.g., neoplasia, diabetes mellitus
- Absolute contraindications
  - patients over 50 years of age
  - patients with other systemic disease e.g., neoplasia, diabetes mellitus
  - patients with active infection
  - patients with peptic ulcer disease
  - patients for whom an alternate form of therapy is possible; e.g., alteration in medical regimen, standard open heart surgery valve replacement, saphenous vein grafting, ventricular aneurysm resection.
  - patients with active myocarditis may be treated with immune suppression on protocol.

2. TRANSPLANT TEAM MEMBERS

The transplant team at Columbia-Presbyterian Medical Center includes the following persons by department:

- Surgery
  - Dr. Eric Rose
  - Dr. Keith Reemtsma
  - Dr. Craig Smith
  - Joann Lamb, M.S.N.
- Cardiology
  - Dr. Ronald Drusin
  - Dr. Dennis Reison

- . Dr. Eric Powers
- . Dr. David Blood

- Neurology
  - . Dr. Matthew Fink
- Psychiatry
  - . Dr. Jeffry Kahn
- Social Work
  - . Gil Ludwig, M.S.W.
- Physical Therapy
  - . Theresa Morrone, R.P.T.

3. PATIENT CONSENT FORMS

All patients at Columbia-Presbyterian are required to sign a consent form (available in either English or Spanish) indicating that they are fully knowledgeable about heart transplantation. The English version of this consent form is included here as Appendix 8-B.

4. EQUIPMENT

A detailed list of equipment required for heart transplant surgery has been provided by the team at Columbia-Presbyterian. The equipment and supplies have been organized according to category. The categories are as follows: general, heart-lung machine, anesthesia machinery, drugs, basic open-heart tray, and other miscellaneous items. The complete list is as follows:

- General
  - . 1 operating room
  - . 1 operating table
  - . 1 large overhead light
  - . 1 4 channel monitor (EKG, 3 pressure channels)
  - . 1 blood gas machine

- . 1 hematocrit spinner
- . betadine
- . 8 sterile drapes

- Heart Lung Machine
  - . 1 oxygenator
  - . 2 reservoirs
  - . 1 pump tubing pack
  - . 1000cc Ringer's Lactate
  - . 7 bottles salt poor albumin
  - . 2 blood sets
  - . 5-6 heparin bottles (1000u/cc.)
  - . calcium 600 mg./unit
  - . bicarbonate as needed to cover pH
  - . 1 cell-saver packs
  - . 3 Mahem J suction lines
  - . 5 luer-lock stopcocks
  - . 1 one-way valve
  - . 1 pressure chamber
  - . 2-3 pressure monitor lines
  - . 1 purge line
  - . Complete scrub suits (1 per person)

- Anesthesia Machinery
  - . 1 gas mixer
  - . 1 ventilator
  - . 6 I.V. sets
  - . 6 stopcocks
  - . 50 syringes (assorted sizes)
  - . 50 needles (assorted sizes)
  - . 2 endotracheal tubes
  - . 1 oral airway
  - . 3 I.V. catheters
  - . 1 pulmonary artery catheter
  - . 3 sets - pressure transducers
  - . 3 sets - pressure tubings
  - . 5 blood transfusion sets
  - . 1 1/2" pink plastic tape
  - . 1 1" paper tape
  - . 1 1" surgical tape
  - . 20 suction catheters
    suction tubing
    alarms
  - . 1 portable EKG/Bp monitor
  - . Main frame amplifier and display
  - . Anesthesia sheets (records)
  - . 8-channel trend recorder
    blood warmer
    blood pump bags
    larygoscope
    guide wire
    defibrillator
    warm blankets

warming mattress
vital sign sheets
drug sheet
Bp cuff and Doppler unit
Capnometer - measures CO_2

. 4 pressure transducers
alcohol pads

- Drugs
  . Pre-meds
    5-10 mg morphine
    0.2-0.4mg. scopolamine
    1 tubex injector
    1 3cc syringes/22 guage needles
  . During Surgery
    Fentanyl 5 mg. I.V.
    Valium 50 mg. I.V.
    Pavulon 20 mg. I.V.
    Droperidol 25 mg. I.V.
    Metubine 40 mg. I.V.
    Solumedrol 500 mg. I.V.
    Protamine 500 mg. I.V.
    Kefzol 1 Gm. I.V.SS
    Heparin 500 mg.
    Calcium Chloride 1 amp.
    Nitroprusside 50 mg/500 cc. D5W
  . Always prepared for transplant--not necessarily used
    Dopamine 200 mg./250 cc. D5W
    Dobutamine 250 mg./250 cc D5W
    Isuprel 1 mg./250 cc D5W
    Lidocaine 300 mg. I.V.

- Basic Open Heart Tray

  <u>Tray #1</u>
  . 2 #7 knife handles
  . 2 #4 knife handles
  . 2 #3 knife handles
  . 2 long mouse-tooth forceps
  . 4 short mouse-tooth forceps
  . 2 short plain forceps
  . 2 skin hooks
  . 3 Malleable retractors
  . 2 brain retractors
  . 2 large loop retractors
  . 2 small loop retractors
  . 8 sponge sticks
  . 3 long needle holders
  . 3 short needle holders
  . 8 tube clamps
  . 24 large Kelly clamps
  . 6 Kocher clamps

- 8 Allis clamps
- 2 Babcock clamps
- 24 mosquito clamps (straight)
- 24 Hopkins clamps
- 18 large towel clips
- 30 small towel clips
- 2 short sponge sticks
- 1 Ankenney retractor
- 1 Scoville retractor
- 1 Finochette retractor
- 12 curved mosquito clamps

General String:

- 2 mixters
- 4 baby Adson
- 8 straight Adson
- 4 straight Adson
- 1 right angle clamp
- 6 long Allis clamps
- 2 Wylies
- 2 DeBakey Cooley clamps
- 2 sternal needle holders
- 2 old needle holders to hold sutures
- 1 long right-angle clamp
- 5 DeBakey cross clamps
- Basin set or 2 large sterile basins
- 3 1000cc iced Ringer's Lactate

Vascular String:

- 1 small Beck clamp
- 1 large Beck clamp
- 3 Halco clamps
- 1 Potts spoon clamp
- 2 curved X-clamps
- 1 angled X-clamps
- 1 large X-clamp
- 1 Kay Lambert clamp
- 1 Hunter-Scanlon clamp
- 1 Glover Statinsky
- 1 Harken clamp
- 1 angled Potts ductus
- 1 larger angled Potts
- 1 straight Potts ductus
- 1 straight coarctation

<u>Tray #2</u>

- 3 nerve hooks
- 2 probes
- 2 Nelson forceps
- 2 Brown Adson forceps
- 2 long DeBakey forceps
- 2 medium DeBakey forceps
- 2 small DeBakey forceps
- 2 long sewing forceps
- 1 short sewing forceps

- 3 long Rummel touniquets
- 1 small Rummel tourniquet
- 3 Yankauer suctions
- 1 baby Yankauer suction
- 1 fenestrated suction tip
- 1 adult pump suction
- 6 IBM suction tips
- 1 pitcher with asepto & bulb syr.
- 2 containers with pledgets and micro peanuts

- 1 Metal Box Containing
  - 1 wooden tongue depressor
  - 1 adapter
  - 1 X-mass tree
  - 1 C clamp
  - 1 heart tip cautery
    plastic Rummels
    #30 wire
  - 1 atrial wires
  - 2 french eye needles
  - 4 glass reels
  - 4 gnats
  - 1 each - lge, med. curved, and straight bulldog
  - 1 ruler
  - 1 teflon felt
  - 5 intra-cardiac retractors
  - 1 laryngeal mirror
  - 1 knitted dacron
- Extras - to be added for all cases
  - 2 #22 blades
  - 2 #10 blades
  - 2 #15 blades
  - 2 #11 blades
  - 1 set umbilical tape
    4 long, 2 short
  - 1 V pack (V 1152)
  - 1 ea. 5-0, 4-0, 3-0, 2-0 tevdek on reels
  - 3-7-914 2-0 Tevdek pre-cut
  - 5 Dexon, either 4-0, 3-0
  - 2 bone wax
  - 5 50cc syringes
  - 6 #20 guage needles either #14 Medicut or 16 guage Medicut to give cardioplegia
  - 6 20cc plastic syringes
  - 1 10cc plastic syringe
  - 4 #18 guage needles
  - 1 package heparin labels
  - 3 long Gerald forceps
  - 3 Russian forceps; 1 long; 1 medium
  - 1 Ferris-Smith forcep
  - 1 long sewing forcep

- 2 Jamieson needle holders - long
- 1 long knife handle
- 1 circumflex artery scissor
- 3 Castroviejo needle holders; 2 straight, 1 curved
- 1 baby clamp
- 2 ronguers; 1 straight, 1 downward
- 1 caliper
- 1 offset needle holder

- Equipment Needed for Transfer to ICU
  - 1 stretcher or bed elevator
  - 1 portable monitor - 4 channel
  - 2 chest tubes
  - 1 pleurevac
  - 1 foley catheter
  - 1 foley bag
  - 1 ambu bag
  - 1 portable oxygen tank and tubing
  - 1 sheet to cover patient
  - Complete scrub suits for each person

5. NUMBER OF TRANSPLANTS

The number of transplants performed at Columbia has fluctuated considerably over the years, with the majority of all procedures performed in the past two years. Table 8-3 shows a breakdown of the number of transplants performed by year.

6. TRANSPLANT PROTOCOL

Like most heart transplant protocols, that followed by the team at Columbia is very similar to the technique of orthotopic heart transplantation first described by Lower and Shumway. The following description has been taken from the Policy and Procedures Manual prepared by the team at Columbia.

The recipient is moved to Room C of the PH 18 OR and appropriate monitoring devices are applied. General anesthesia is then induced and a median sternotomy is performed to expose the

Table 8-3
Number of Heart Transplants Performed By Year At
Columbia-Presbyterian Medical Center

YEAR	NUMBER OF PROCEDURES
1977	3
1978	6
1979	0
1980	4
1981	1
1982	7
1983	16

heart. The pericardium is opened widely and tapes are placed about both vena cavae, the aorta and the pulmonary artery.

Cannulation of the recipient for cardiopulmonary bypass is similar to standard techniques for most open cardiac surgical procedures. The arterial cannula is inserted as distally as possible in the ascending aorta. The atrial cannulae are both placed in a lateral position in the high right atrium. After institution of cardiopulmonary bypass and exclusion of the atrial cannulae with snares placed around the superior and inferior vena cavae, the ascending aorta is crossclamped and both great vessels are then divided at the level of the commissures of the semilunar valve. The aorta and main pulmonary artery are separated by division of the visceral pericardium to provide maximum exposure and mobility. The atria are transected immediately above their atrioventricular grooves, but posterior to the level of the atrial appendage, since these structures constitute potential sites of postoperative thrombus formation.

Implantation of the graft begins with the left atrium. The donor left atrium is opened by connecting incisions through the pulmonary veins. The left atrial anastomosis is then begun with placement of one end of a 3-0 prolene at the entrance of the recipient's left superior pulmonary vein and the second limb of the suture in the base of the donor heart's left atrial appendage. A running suture line is then placed on the inside and carried along the inferolateral aspect of the left atrium to the point of junction with the interatrial septum. The second limb of the suture is then carried superiorly

along the roof of the left atrium and then down the interatrial septum to join the first limb of the suture.

As soon as feasible, continuous pericardial lavage with cold saline 3-4^{o}C, is initiated during the left atrial anastomosis in order to maintain myocardial hypothermia. The donor right atrium is then opened by an incision extending from the orifice of the inferior vena cava upward in a curvilinear fashion into the base of the right atrial appendage. This technical modification, first described by Barnard, removes the donor sinoatrial node from proximity or incorporation in the suture line and furthermore, preserves two of the major internodal pathways that have been described by James. The sinus rhythm of nearly all patients, therefore, remains normal postoperatively.

After the donor right atrium is incised, the tricuspid apparatus is inspected and a right ventricular endomyocardial biopsy is removed to serve as a control for subsequent biopsies of the graft. Anastomosis of the right atrial wall is begun at the lower end of the interatrial septum, using a second 3-0 prolene. This is first advanced inferiorly around the orifice of the inferior vena cava and then upward along the anterolateral border of the right atrium to approximately its mid portion. The second half of the suture is then carried up the interatrial septum, along the superior margin of the right atrium, and then down the lateral border to the point of termination of the first limb of the suture.

The left atrial appendage is then cannulated with an additional line for infusion of cold saline in order to induce further cooling of the left ventricle during the aortic anastomosis as well as

to displace air from the left atrium and ventricle. The donor and recipient pulmonary arteries and aortas are then joined with a 4-0 prolene sewing the back wall in a running manner from the inside and completing the anterior aspect from the outside. Immediately prior to completion of the aortic anastomosis additional attempts are made to displace air trapped in the left-sided cardiac chambers by manual manipulation of the heart and inflation of the lungs. After removal of the aortic crossclamp, the cold saline infusion line in the left atrial appendage is removed. Spontaneous defibrilation of the heart may occur; if not, defibrillation is accomplished with countershock. A needle vent site is placed in the ascending aorta for further evacuation of air. After an appropriate period of continued cardiopulmonary bypass support for complete resuscitation of the graft, cardiopulmonary bypass is discontinued after beginning an isoproterenol infusion at a rate of 1-2 ug/min. The rate of infusion of isoproterenol is titrated to increase heart rate to approximately 110 beats/min.; this chronotropic effect, as well as the inotropic effect of isoproterenol, significantly increases the output of the donor heart. Two temporary pacing wires are placed in the donor right atrium, if necessary. On 3 occasions we have used atrial pacing at a rate of 400-600 cycles/minute to successfully convert atrial flutter to sinus rhythm during episodes of acute rejection.

If the patient was on a standard intra-aortic balloon pump which involved the sewing of a dacron graft to the femoral artery, and it can be demonstrated that the patient can now maintain satisfactory hemodynamics without the aid of the balloon, then the balloon is removed and after appropriate use of a Fogarty catheter, the remaining

graft is then oversewn or removed. The wound is copiously irrigated with neobacin solution and tightly approximated and dressed with a dry sterile compression dressing. If the patient was on a percutaneous intra-aortic balloon pump, it is advisable that the patient be taken to the recovery room on the assist and that this device be removed the following day simply by drawing a vaccuum and removing the balloon percutaneously with the application of 30 minutes of external pressure and then a compression dressing.

7. NATIONAL HEART TRANSPLANTATION STUDY DATA COLLECTION

The Battelle study team owes a great deal to the staff of Columbia-Presbyterian Medical Center who have so graciously assisted with the collation of the data for the study. The collection of data at Columbia was a complex task owing to the organizational separation of the Columbia-Presbyterian Medical Center and the Columbia Presbyterian Hospital. The following persons shared primary responsibility for the data collection effort:

- Laura Seche, R.N., M.S.N.
- Fiorella Vataj, R.N.
- Joann Lamb, M.S.N. (on-site project coordinator)
- Eric Rose, M.D. (on-site principal investigator)

D. MEDICAL COLLEGE OF VIRGINIA

With the relocation of Dr. Richard Lower from Stanford University Medical Center to the Medical College of Virginia (MCV) in 1967, plans were made to initiate cardiac transplantation. Under the direction of Dr. David Hume, MCV had already established a strong renal

transplantation program. In May, 1968, MCVs first clinical cardiac transplantation was performed. The patient died at 7 days of acute rejection. The second case was performed in August, 1968 and survived for six and one-half years. Three subsequent cases were performed between October, 1968 and February, 1970 with all three patients dying in less than two months due to acute rejection. In 1973, following a hiatus while the program awaited the legal definition of brain death to be established (Lower vs. Tucker; Virginia Equity Court), cardiac transplantation was again initiated with seven cases performed between July, 1973 and March, 1976. One long-term survivor (two and one-half years) emerged from this group.

The MCV group has made numerous noteworthy contributions to the field of cardiac transplantation. Among these have been the following: (1) initiation of long distance cardiac procurement in 1977, and (2) the institution of rabbit antithymocyte globulin and immune monitoring. The cardiac transplantation program of the Medical College of Virginia has a long and in-depth experience in all phases of cardiac transplantation.

The MCV team has remained active over the years. Between 1968 and 1976, 13 cases were performed. Between May, 1977 and February, 1981, 27 additional transplants were performed. In 1983, 20 heart transplants were performed.

1. PATIENT SELECTION CRITERIA

Consistent with other programs, the Medical College of Virginia team is very selective in choosing candidates for cardiac transplantation. In general, patients are considered eligible if they meet the criteria specified below:

- documented Class IV heart failure
- limited life expectancy
- no other conceivable surgical or medical procedure available to prolong life
- less than 50 years old
- calculated pulmonary status for adherence to a continued medical regimen and follow-up program as well as for re-establishment of the recipient as a successful working member of society
- willingness of the patient, the referring physician and the patient's family to accept a 40 percent three month mortality, the implications of long term immuno-suppression, and a firm understanding of acute and chronic rejection injury and the morbidity associated with Cushing's syndrome

Patients with the following characteristics are considered at risk for heart transplantation:

- presence of significant peripheral vascular disease
- presence of insulin-dependent diabetes mellitus
- presence of objective evidence of recent pulmonary embolism or source

2. TRANSPLANT TEAM MEMBERS

The staff listed here make up the heart transplant team at the Medical College of Virginia.

Cardiology

- Dr. Michael Hess, M.D., Professor of Medicine
- Dr. Andrea Hastillo, M.D., Associate Professor of Medicine

- Roxanne Haddon, Secretary
- Sheelah Ryder, R.N.

Cardiac and Thoracic Surgery

- Richard Lower, M.D., Professor of Surgery and Division Chairman
- Timothy Wolfgang, M.D., Assistant Professor of Surgery
- Kevin Ducey, M.D., Assistant Professor of Surgery
- Szabolcs Szentpetery, M.D., Associate Professor of Surgery
- John Capehart, M.D., Cardiac Fellow
- Diane Sansonetti, M.D., Cardiac Fellow

Transplant and Vascular Surgery

- H.M. Lee, M.D., Professor of Surgery and Division Chairman
- Gerardo Mendez-Picon, M.D., Associate Professor of Surgery
- Mitchell Goldman, M.D., Associate Professor of Surgery

Tissue Typing Laboratory

- T. Mahanakumar, Ph.D., Associate Professor and Director of Tissue Typing

Donor Selection

- Cary Suter, M.D., Neurologist

Cardiac Transplant Program

- Herb Teachey, Jr., Administrator Coordinator
- Ann Martin, R.N., Coordinator
- Pat Chappell, Administrative Assistant

Clinical Research Center

- Mary Claire Darden, Administrator
- Margaret Carter, R.N., Nursing Supervisor
- Alice B. Allison, LPN
- Mattie Carter, Hospital Aide
- Clarice Clark, Secretary
- Peggy L. Farmer, R.N.
- Nancy James, Hospital Aide
- Sandra Jennings, Dietician
- Roberta Johnson, Kitchen Aide
- Hildegard Kantor, Lab Technician
- Ference Kantor, Lab Technician
- Shirley Kelsaw, Kitchen Aide
- Burnell Maddox, R.N., Head Nurse
- Phyllis Marszalek, R.N.
- Sharon Nomdy, R.N.
- Eleanora Owens, Kitchen Aide
- Mable Payne, LPN
- Dana Powell, R.N.
- Bernice Seay, Kitchen Aide
- Mary R. Smith, LPN
- Kathleen Sullivan, R.N.
- Joy Taylor, R.N.
- Rosie Woods, Hospital Aide

Counsulting Departments

- Department of Anesthesia
- Department of Dermatology

- Department of Dietetics
- Department of Medicine
  - Division of Gastroenterology
  - Division of Infectious Diseases
  - Division of Pulmonary Medicine
- Department of Occupational Therapy
- Department Otolaryngology
- Department of Pathology
- Department of Pharmacy
- Department of Physical Therapy
- Department of Psychiatry
- Department of Social Work
- Department of Surgery
  - Division of Oral and Maxillofacial
  - Division of Orthopedics
- Department of Radiology

Nursing Services Utilized

- Cardiac Surgery ICU, 4th Floor, Main Hospital
- Respiratory ICU, 4th Floor, Main Hospital
- General Medicine ICU, 4th Floor, Main Hospital
- Central Medicine Floor, 10th Floor, Main Hospital
- Clinical Research Floor, 4th Floor, West Main Hospital
- Operating Room Nursing
- Recovery Room Nursing

3. PATIENT CONSENT FORMS

Prior to transplantation, all candidates for heart transplantation are required to sign a consent form indicating that they are knowledgeable about the risks associated with heart

transplantation. A copy of the consent form used at MCV is attached as Appendix 8-C

4. EQUIPMENT

The MCV team was asked to provide a complete list of all equipment and facilities required for heart transplantation. The list they provided is reproduced below.

- Tissue Typing Laboratory
  - . Centrifuges
  - . Hood
  - . Luuoro Microscope
  - . Carbon Diaoxide Incubator
  - . Flow Cytometer
  - . Apple Computer
- Clinical Research Center
  - . Electrocardiographic Hardwire Monitoring
  - . 12 lead EKG machine
  - . Core laboratory
- Procurement Equipment
  - . Sterile Ice
  - . Cooler
  - . Standard Open Heart Tray
  - . Specimen Containers
  - . Baggogets
- Operating Room
  - . Pressure Monitoring for Swan Ganz and Arterial Line
  - . Aortic Balloon Pump
  - . Standard EKG Equipment
  - . Pacemaker Equipment
  - . Hypothermia Unit
  - . Defibrillator
  - . Heart-Lung Bypass Pump
  - . Epicardial Pacing Wire
  - . Basic Open Heart Set

    Retractors
    - . 1 Small Richardson
    - . 1 Medium Richardson
    - . 1 Tapered Malleable
    - . 2 Cushing Vein
    - . 2 Little Vein
    - . 1 Army Navy
    - . 2 Weitlanders
    - . 1 Morse Sternal

    Bottom of Basket
    - . 1 Needle Boat
    - . 1 Wire Cutter
    - . 1 4-Prong Rake
    - . 1 Wire Twister

- 2 Extra Long Wire Needle Holders
- 1 Long Russian Forcep
- 1 Long Debakey Forcep
- 1 Long Broad Tip Debakey
- 2 Rummel Tourniquet Stylets
- 2 Tonsil Suction Tips
- 1 #4 Penfield Dissector
- 1 Nerve Hook
- 1 Metal Ruler
- 1 Lambert Kay Clamp
- 1 Tube of 1/2 Length 18ga Wire

12" Stringer
- 1 Sponge Stick
- 4 KD Clamps
- 5 Tubing Clamps
- 8 Edna Clamps
- 2 Hemoclip Appliers
- 1 Spoon Potts Clamp
- 1 Favaloro Clamp
- 1 Right Angle
- 3 Tonsil Clamps
- 2 Kelly Clamps
- 3 Curved Hemostats
- 12 Curved Mosquitoes
- 1 Baby Right Angles
- 2 6" Mayo Hegar Needle Holders
- 2 8" Mayo Hegar Needle Holders
- 2 7" Vascular Needle Holders
- 1 Tubing Scissor
- 1 Straight Potts Scissor
- 2 Straight Mayo Scissors
- 1 Curved Mayo Scissor
- 2 Metzenbaum Scissors
- 1 Long Curved Mayo Scissor
- 1 Curved Mayo Scissor
- 1 Curved Nelson Scissor
- 2 Long Vascular Needle Holders
- 1 Right Angle
- 1 Favaloro Clamp
- 5 Tonsil Clamps
- 2 Kelly Clamps
- 12 Curved Mosquitoes
- 3 Curved Hemostats
- 4 Long Allis Clamps
- 4 Short Allis Clamps
- 2 Long Oschners
- 14 Short Oschners
- 3 Sponge Sticks
- 1 Semb Right Angle

Towel Clip Stringer
- 24 Towel Clips
- 24 Baby Towel Clips

Wrapped in Towel
- 3 Short DeBakey Forceps
- 1 Short Broad Tip Debakey Forcep
- 1 Stille Forcep with Teeth
- 1 Stille Forcep without Teeth
- 2 Brighams
- 2 Adsons with Teeth
- 1 Frazier Suction Tip
- 3 #3 Knife Handles
- 4 #7 Knife Handles
- 1 #3 Long Knife Handle

Lay Across Top
- 1 Cloth Covered Satinsky Clamp
- 2 Cloth Covered Beck Aortic Cross Clamps

- Cardiac - All Surgeons
  - General Surgery Pack
  - Perineal Pack
  - Chest Pack
  - 4 Gown Pack
  - Minor Basin
  - Specimen Pan
  - Graduages x2
  - Laps x10
  - K.D.'s x2
  - 4 x 4's x1
  - Suction Bottles x3
  - Unsterile Suction Tubing x2
  - Magnetic Needle Counter
  - Mag Pad
  - Light Handles
  - Bovie Pencil
  - Grounding Pad
  - Prep Kit
  - Prep Sponges
  - Pleur Evac
  - Foley Catheter Tray
  - 15fr/5cc Foley
  - Urinemeter
  - Open Heart Tray
  - Saw Tray
  - Internal Defib Cord
  - Adult Internal Defib Paddles
  - Large Empty Instrument Basket
  - K - Thermia Blanket
  - Specimen Bowl

5. NUMBER OF HEART TRANSPLANTS

The MCV team averages 7-8 heart transplants per year. Table 8-4 provides a yearly breakdown of the number of procedures performed since 1968.

6. TRANSPLANT PROTOCOL

In 1960, Lower and Shumway first reported the surgical technique that has remained the standard technique for orthotopic cardiac transplantation. This technique, as described, continues to be fllowed at the Medical College of Virginia. Details of the postoperative care plans for heart transplant recipients at MCV are provided below.

a. Immediate Post-Operative Care. At the time of surgery immunological suppression of the patient begins consisting of 100 mg of intramuscular ATG (rabbit antithymocyte globulin) and 1.5-2.0 mg/kg azathioprine. Following transplantation the patient receives 500 mg of intravenous methylprednisolone and is taken to the cardiac surgical intensive care unit, Room 8-036, which has previously been prepared for strict reverse isolation. In the immediate 24-48 hours post-surgery, the patient is continuously attended by two full-time nurses with strict isolation procedures maintained. If necessary, epicardial pacing and positive inotropic support is continued. It is the philosophy of Drs. Lower and Wolfgang to attempt aggressive post-operative ambulation with removal of all in-dwelling catheters and endotracheal tubes as soon as possible. It is anticipated that within 24 hours the patient is awake, alert, sitting at the edge of the bed and begun on oral feedings. The immunosuppressive protocol at this time includes 100 mg of ATG IM daily X 5, azathioprine continued

Table 8-4
Number of Heart Transplants By Year At The
Medical College of Virginia

YEAR	NUMBER OF PROCEDURES
1968	4
1969	0
1970	1
1971	0
1972	0
1973	3
1974	2
1975	2
1976	1
1977	6
1978	8
1979	5
1980	7
1981	5
1982	6
1983	8

at 1.5-2.0 mg/kg and the institution of oral prednisone at 1 mg/kg. The patient receives tapering doses of methylprednisolone at 500, 250, and 100 mg BID for the first three days. Every four hours external electrocardiographic voltage is monitored on an electrocardiogram machine which is used exclusively for the transplant patients. With stabilization of the patient on the oral immunosuppressive program, withdrawal of all in-dwelling catheters, and the beginning of ambulation, the patient is then transferred to the Clinical Research Unit on West-4-South. The patient is initially placed in Room 4-036 which has a full-time electrocardiographic monitoring facility. At this time the patient enters a second antithymocyte globulin protocol and immuno-monitoring protocol with daily T-lymphocyte counts performed and antithymocyte globulin therapy given as indicated. Dosage is adjusted to the level of total circulating T-cells according to the method of Thomas et al. During this period of time the patient enters a formal program of physical therapy, the psychiatric social workers continue to follow the patient, and occupational therapy, the pastoral services and social services are consulted as necessary. The patient is encouraged to begin and to maintain a program of progressive ambulation and exercise while skilled paramedical personnel direct the program and document a stable electrocardiographic rhythm by continuous monitoring with exercise along with blood pressure determinations.

As immunosuppressive medications are decreased, the patient is transferred to one of the single rooms in the Clinical Research Unit. By this time isolation procedures consist only of mask and gloves for the patient and for visitors, nurses, physicians and paramedical personnel visiting the patient. The immunological program

at this time will consist of azathioprine stabilized between 1.0-1.5 mg/kg to a level of bone marrow and hepatic tolerance. The prednisone dose, initially begun at 1 mg/kg, has been tapered to 2.5 mg per week to 0.3-0.5 mg/kg and the antithymocyte globulin protocol completed. Adjunct therapy at this time consists of Persantine 50 mg tid, Iron Sulfate 300 mg tid, Folate 1 mg qd, antacids and potassium supplementation. According to the current protocol, the patient remains on the Clinical Research Unit between 8-10 weeks post-operatively for stabilization of immunosuppressive therapy, monitoring during the high risk period of infection, and for careful electrocardiographic and echocardiographic monitoring for evaluation of rejection. Should the diagnosis of rejection be suspected (documented 20% decrease in summated electrocardiographic voltage, a 50% increase in left ventricular mass by echocardiogram, and/or constitutional symptoms compatible with the disease), the patient is immediately taken to the cardiac operating room where a right ventricular endomyocardial biopsy is performed. If the diagnosis of moderate to severe rejection is present with confirmation by the endomyocardial biopsy, the patient will receive pulsed methylprednisolone therapy consisting of gram per day IV over 30 minutes x 3 days. The patient will then be re-biopsied at the end of 7-10 days. At the beginning of the 8th week, if the patient is stable, progressive ambulation to sitting rooms within the hospital and then ambulation in the community is begun. Between 8-10 weeks the patient is on a stable immunological protocol and if there is no evidence of either rejection or infection, the patient is returned to the care of the family physician. During this time period, careful individual consultation and communication

with the referring physician is continued. The referring physician has agreed to closely monitor the patient with a weekly electrocardiogram, complete blood count, platelet count, reticulocyte count and has agreed to become an integral part of the MCV protocol.

This protocol is continued during the first year when the patient is at a higher risk for rejection. During this time period the prednisone dose is tapered to approximately 0.4 mg/kg per day, azathioprine is maintained and adjunctive therapy with persantine 50 mg tid is maintained. If the referring physician documents a 20 percent decrease in electrocardiographic voltage and/or a 50 percent increase in left ventricular mass by echocardiography, one of two options are open: the patient can either receive bolus methylprednisolone in the home environment, or preferably, the patient is referred back to MCV for endomyocardial biopsy to confirm rejection and to treat the rejection episode. During the treatment of rejection, the patient is carefully monitored for development of systemic infection. Following successful treatment, the patient again returns home.

Routinely at six months post-transplantation the patient returns to MCV and enters the long term follow-up Protocol #3.

b. Long Term Evaluation of the Patient with Orthotopic Cardiac Transplantation. At six months post-transplant and every 6-8 months thereafter, the patient returns to MCV for a complete evaluation and is entered into the protocol of long term study of the transplanted heart. The patient is admitted for a four day hospitalization to the Clinical Research Unit. A complete history and physical examination is performed. Routine laboratory work includes CBC and differential, platelet count, reticulocyte count, urinalysis, clinical chemistry

screen (SMA-20), T-cell rosettes and B-cell antibodies. Particular attention is paid to the extent of the induced Cushing's syndrome (presence or absence of diabetes mellitus, proximal muscle weakness, back pain, self-image, etc.), the home and social situation, interaction with family, physicians and the community and the patient's success in returning to work. The functional integrity of the graft is evaluated by the following protocol:

1) Electrical Activity: Standard 12-lead ECGs are obtained and the stability of the summated voltage is compared to prior tracings; the appearance of Q waves, ST segment changes and the presence or absence of atrial and ventricular ectopy is sought. Twenty-four hour Holter monitoring is obtained particularly looking for complex ventricular ectopy and stability of the A-V conduction system. This protocol is based on an analysis of over 1,300 electrocardiograms and 1,000 hours of Holter monitoring and has preliminary identified the presence of complex ventricular ectopy as a significant risk factor for sudden death in the transplant patient.

2) Bruce protocol stress testing and exercise thallium perfusion studies: This study permits evaluation of both exercise capability (and therefore both graft function and the intact cardiovascular system), extent of proximal muscle weakness and indirectly, coronary perfusion. During the exercise portions of the test, the presence or absence of ST segment depression, ventricular ectopy and maximal attainable heart rate is monitored.

Since the transplanted heart is denervated, the patients do not experience angina and therefore ST segment changes and perfusion defects provide objective criteria for possible accelerated coronary atherosclerosis during stress testing. Using this protocol, over 50 exercise treadmill tests have been performed with no complications. Following the exercise portion of the test, the Thallium perfusion study is done, both immediately post-exercise and four hours later during the rest/redistribution phase. To date, new regional perfusion abnormalities have correlated with angiographic documentation of obstructive coronary artery disease and normal perfusion studies have correlated with an excellent 6 month graft prognosis.

3) Gated Pool Scans (MUGA): Rest/Exercise Gated pool scans are obtained to evaluate regional wall motion, ejection fraction and cardiac output. To date, the gated pool scan has been extremely reliable in confirming the hyperdynamic early phase (year 1) of the transplanted heart, the acute reduction of ejection fraction with the onset of acute rejection, and the appearance of regional wall motion abnormalities of ischemic rejection. Review of the exercise Thallium studies and gated pool scans will dictate the need for invasive arteriography. In the MCV experience, a normal (no change) Thallium study and gated pool scan carries

an excellent 6 month prognosis and obviates the need for coronary arteriography.

4) M-mode and 2-dimensional Echocardiography: An increase in left ventricular mass by M-mode echocardiography has been found to correlate well with acute rejection and has resulted in the working hypothesis that the disease of cardiac rejection is a form of inflitrativew restrictive cardiomyopathy. This data base has been established in over 100 M-mode echocardiograms and the concept is currently being utilized in other institutions for the noninvasive diagnosis of rejection. Furthermore, echocardiography permits the noninvasive evaluation of chamber size, myocardial contractility, the presence or absence of pericardial disease and an indirect evaluation of myocardial contractility.

5) Serum lipid determinations: Eighteen-hour fasting serum lipid profiles (total cholesterol, triglycerides, and HDL cholesterol) are obtained and the risk ratio (total cholesterol/HDL cholesterol) calculated. If the risk ratio calculates at greater than 5.0, it has been the MCV experience that these patients are at higher risk for accelerated atherosclerosis. The identification of this risk factor will necessitate diet modification and/or drug therapy (colestipol) aimed at the reduction of total cholesterol, and a more aggressive exercise

program aimed at increasing HDL cholesterol. The ultimate benefit of this intervention has yet to be tested.

6) Right venticular endomyocardial biopsy: This permits the longitudinal study of changes in muscle architecture, determination of the presence or absence of lymphocyte infiltration, and serves as the objective guide to immunosuppressive therapy. In addition, occasionally intramyocardial arteriolar structure can be directly visualized and serve as a guide to therapy and prognosis.

7) Coronary arteriography: If indicated, patients will undergo right and left heart catheterization, ventriculography and coronary arteriography for the identification of graft function and altered coronary artery anatomy. To date, six patients have undergone post-transplantation cardiac catheterization without any complications.

In conclusion, all patients alive at six months post-transplant have entered the long-term evaluation protocol at MCV. This protocol is funded by the Clinical Research Unit and includes travel expenses if necessary. To date MCV has had 100% patient compliance with this protocol. Both the patient and the referring physician greatly appreciate the guidelines and counseling provided by this semi-annual "check-up" and provide the transplant program with excellent long-term follow-up of the patient. The patient's physician receives a complete summary of all data obtained at the time of the

long term follow-up visits and remains an integral influence on any changes in the patient's medical regimen when indicated.

7. THE NATIONAL HEART TRANSPLANTATION STUDY DATA COLLECTION

Considerable effort was required to compile all the data on MCV patients for the National Heart Transplantation Study. Although the majority of the data collection tasks were performed by Ms. Margy Goldman, she received assistance from Andrea Hastiollo, M.D., and Michael Hess, M.D. Dr. Hess served as the on-site principal investigator and Ms. Goldman as the on-site project coordinator.

E. UNIVERSITY OF MINNESOTA

The cardiovascular surgery program at the University of Minnesota began in 1953 when the world's first open intra-cardiac surgical procedure was performed at this institution by Dr. F. John Lewis, utilizing a deep hypothermia technique. The leadership of Dr. Richard Varco and Dr. C. Walton Lillihei resulted in a flourishing and innovative program in cardiovascular surgery at the University of Minnesota and the emphasis has always been placed on the development and assessment of new techniques and ideas in cardiovascular surgery in addition to providing excellence in clinical care and teaching.

During the course of his residency, training and faculty appointment in cardiovascular surgery at the University of Minnesota, Dr. Norman Shumway laid groundwork in basic research that would later result in the successful clinical cardiac transplant program that he has developed at Stanford University. Dr. Shumway and Dr. Christiaan Barnard, both pioneers in cardiac transplantation, received their training at the University of Minnesota.

In 1967, Dr. John S. Najarian succeeded Dr. Owen Wangensteen as Professor and Chairman of the Department of Surgery. Since that time the University of Minnesota has developed into the largest clinical transplant program in the world and has always emphasized that success in clinical transplantation lies on a solid base of basic immunologic research and a strong collaborative effort between the various disciplines that are involved in the care of the transplant patient.

As renal transplantation developed and became an established clinical mode of therapy, interest in transplantation of other organs was explored, both at the University of Minnesota and at many other institutions. In the late 1960's based on the earlier work of Shumway and Barnard, Dr. Aldo Castaneda and Dr. J. Ernesto Molina began a series of studies in primates on cardiac transplantation. Their work was primarily concerned with autonomic regulation of the transplanted heart and sought to answer a variety of physiologic questions that appeared to be of great importance prior to the clinical use of cardiac transplantation. While other centers jumped ahead and began performing clinical cardiac transplants, the University of Minnesota concentrated on more basic aspects of the problem and sought the answers to questions relating to the basic rejection phenomenon, the physiology of the transplanted heart, and the control of infectious complications. Failure to recognize and deal with these problems had resulted in repeated failure in the earliest attempts at cardiac transplantation and a loss of interest in the procedure by most groups.

Because of Dr. Shumway's close relation to the faculty at the University of Minnesota, his work, which was based on a sound basic approach and careful observation and followup, was observed with

interest. As the results of the Stanford group steadily improved, it became apparent that cardiac transplantation did indeed offer a viable option for those patients who were carefully selected with various forms of end-stage cardiac disease. The expertise to deal with the problems unique to the cardiac patient was carefully developed, and in 1978 the University of Minnesota performed its first clinical cardiac transplant. This patient survived the procedure quite well, but returned some three months later with a devastating fungus infection and succumbed. Within the next 18 months, two additional transplants were performed and one of these patients remains a long-term survivor.

After three cardiac transplants had been performed, it was elected to reassess the program completely and establish a one year moratorium so that new input from each group could be examined. At the end of this one year moratorium, it was decided that clinical cardiac transplantation indeed appeared to be a form of therapy that could be applied to very selected patients with the expectation that they could resume a reasonably normal life style both from a physical and psychological sandpoint and that a favorable cost/benefit ratio could be achieved.

The University of Minnesota cardiovascular program includes the University Hospital, where approximately 350 open cardiac procedures are performed annually. Other components of the cardiovascular program include the Minneapolis Veteran's Administration Medical Center, where approximately 150 open cardiac procedures are performed annually, Ramsey County Medical Center, where approximately 100 open cardiac procedures are performed annually, and the Hennepin County-Metropolitan Medical Center complex, where approximately 400

open cardiac procedures are performed annually. The latter three institutions are concerned almost entirely with adult-acquired disease and a heavy percentage of the cases are coronary artery bypass procedures. Both Ramsey and Hennepin County Medical Centers serve as trauma referral centers for the metropolitan Twin Cities' area and for this reason a significant percentage of the surgery done there is either related to traumatic injuries or to acute events secondary to ischemic heart disease. In contrast, the University of Minnesota Hospital is a tertiary care referral center and approximately 40% of the open cardiac procedures that are performed are in the infant and pediatric age group for various forms of a congenital heart disease. There are also 125 closed procedures performed at the University Hospital for various infant and pediatric age group congenital defects. The balance of the operative procedures performed at University Hospital consists of coronary artery bypass (30%), valve replacement (25%), and specialized procedures such as electrophysiological surgery for the control of arrhythmias and cardiac transplantation.

1. PATIENT SELECTION CRITERIA

Candidates for cardiac transplantation must meet a very strict patient selection protocol. In order to be included as a potential candidate, a patient must meet the following general criteria.

- clinical Class IV symptoms
- failure of available medical and surgical management techniques
- less than 55 years of age

Patients are excluded from consideration if they have any of the following absolute contraindications.

- pulmonary hypertension; mean pulmonary pressure 60 mm/Hg, pulmonary vascular resistance 8-10 units
- presence of malignancy
- presence of active infection
- recent pulmonary infarct
- presence of any terminal or severely debilitating disease process not correctable by cardiac transplant

In addition, patients may be excluded from heart transplantation should they have any of the following conditional contraindications.

- severe chronic obstructive pulmonary disease
- insulin dependent diabetes mellitus

2. TRANSPLANT TEAM MEMBERS

Like most transplant teams, that of the University of Minnesota is large and diverse consisting of individuals who are regular team members and others who are available for consultation. The primary team members, according to department, are as follows:

Surgery

- R. Morton Bolman, III, M.D.
- Ernesto Molina, M.D.
- Robert W. Anderson, M.D.

Cardiology

- B. Levine, M.D.
- J. Schwartz, M.D.
- J. Cohn, M.D.

Nursing

- SICU Nursing Staff
- Cardiac Cath Lab Nursing
- Cardiac Surgery Ward Nursing
- Cardiovascular Nurse Clinician
- Heart Transplant Coordinator
  - Barbara Elick

Social Services

- Pam Riley

Outpatient Clinical Staff

- Marilyn Strand, M.D.
- Barbara Elick

3. PATIENT CONSENT FORMS

Prior to transplant, all candidates for cardiac transplantation are required to sign a consent form. A copy of the consent form is included as Appendix 8-D.

4. EQUIPMENT

The University of Minnesota did not provide a complete list of the equipment and supplies required for cardiac transplantation.

5. NUMBER OF HEART TRANSPLANTS PERFORMED

There has been a steady increase in the number of heart transplants performed at the University of Minnesota. Table 8-5 shows a yearly breakdown of the number of procedures performed.

Table 8-5
Number of Heart Transplants By Year At The
University of Minnesota

YEAR	NUMBER OF PROCEDURES
1976	0
1977	0
1978	3
1979	0
1980	2
1981	4
1982	6
1983	13

6. TRANSPLANT PROTOCOL

The heart transplant protocol followed at the University of Minnesota is similar to that followed by other cardiac transplant programs. The description that follows was provided by the University of Minnesota team.

a. Harvest of the Donor Heart. Through a midline sternotomy, the donor heart is inspected for suitability for transplantation. If deemed acceptable, removal of the donor heart proceeds. Hearts may be harvested at a distance or locally at the University of Minnesota Hospital. If at a distance the harvest is performed without cardiopulmonary bypass. If harvested locally in conjunction with kidneys and/or pancreas, the harvest is removed utilizing extracorporeal circulation. Following administration of heparin, bypass is accomplished via venous catheters placed, one into the superior vena cava directly and another into a femoral vein, and via arterial cannulation of a femoral artery. Once on bypass the cavae are doubly ligated and divided. Elevation of the heart then reveals the pulmonary veins which are individually divided outside their entry into the left atrium, allowing removal of the entire organ. Cardioplegic solution at four degrees centigrade is infused into the aortic root immediatly following aortic cross clamping. The aorta and pulmonary artery are transected and the heart removed. The heart is then immersed in iced saline for transport to the adjacent operating suite where re-implantation will take place.

Following removal of the heart, harvesting of the kidneys and pancreas and the necessary attendant dissection can be undertaken with the cardiopulmonary bypass apparatus still functioning. When these procedures have been accomplished, bypass is terminated.

b. Removal of the Recipient Heart. As soon as visual inspection and evaluation of the donor heart has determined it to be suitable for use, the recipient is subjected to midline sternotomy. Following dissection of the aorta from the pulmonary artery over an adequate distance, heparin is administered (300 u/kg) and cannulation proceeds. Arterial inflow is through a catheter placed high in the ascending aorta. Venous inflow is through a catheter placed directly in the superior vena cava, before its entry into the right atrium (RA) and through another catheter placed into the inferior vena cava through a purse-string low in the RA near the interatrial groove. Bypass is then begun. Both cavae are then snared with tourniquets about the catheters. The aorta is then cross-clamped and cooling proceeds down to 28^{o}C. The RA is then incised at a site below the SA node and approximately 1/2 cm below the junction of the superior vena cava with the atrium and the incision is carried along the inter-atrial groove to the inferior vena cava. Right atrial transection continues with the cephalad portion of the incision being extended into the aortic root and this incision connected with the right atrial incision. The coronary sinus is next divided longitudinally to the atrial

septum which is incised leaving only a posterior rim for future anastomosis. At this point a left ventricular vent is placed through an incision in the apex for decompression. The aorta is transected 3-4 mm above the aortic valve and pulmonary artery is likewise divided just above the pulmonary valve. The left atrium is now further incised until the left pulmonary veins are reached. The incision joins the one already begun in the coronary sinus leaving the pulmonary veins attached to the posterior wall of the left atrium. This allows removal en bloc of the entire organ.

c. Implantation of Donor Heart. The donor heart is removed from cold saline and the left atrium is opened by incisions connecting all four pulmonary veins. Aorta and pulmonary artery are tailored for proper fit. Finally, an incision is carried from inferior vena cava to the tip of the right atrial appendage. The heart is then placed in the pericardial sac and anastomosis is begun between donor and recipient left atria using 4-0 Prolene suture and starting between the left pulmonary veins. These sutures are carried around to the septum which is then anastomosed to the recipient septum, completing the left atrial reconnection. The aortic anastomosis is then accomplished in order to minimize the time of myocardial ischemia. A small incision is made in the ascending aorta, the lungs inflated and the left ventricle manipulated to remove air into the aortic root. The aortic cross clamp is then released allowing perfusion of the coronary arteries. With the infusion of blood, the heart

will usually commence beating within a few moments. Beginning again at the interatrial septum, the right atrial anastomosis is accomplished. Prior to completion of this anastomosis, the pulmonary arteries are joined. The right atria are then closed with care to remove all air. At this point rewarming to 37°C has occurred, the caval snares are released and ventilation resumes. Bypass can now be discontinued. Temporary atrial and ventricular pacing wires are sewn into position, and a left atrial line is placed for post operative hemodynamic monitoring. The chest is closed over two medistinal catheters. Isuprel is begun as a slow continuous infusion to maintain a rate of 100 or greater in the now-denervated heart. This completes the operative procedure for orthotopic cardiac transplantation.

7. NATIONAL HEART TRANSPLANTATION STUDY DATA COLLECTION

Considerable effort was required to collate the data for this study. At the University of Minnesota, all data collection activities were performed by

- Marilyn Strand, M.D.
- Barbara Elick (on-site project coordinator)
- R. Morton Bolman, III, M.D. (on-site principal investigator)

F. UNIVERSITY OF PITTSBURGH

The first heart transplant at the University of Pittsburgh was performed in 1968 by Dr. Henry T. Bahnson. Subsequent to that procedure, relatively few heart transplants were performed at

Pittsburgh until 1980, when three procedures were undertaken. Since that time, however, Pitttsburgh has become the second most active heart transplant center in the United States. In 1983, a total of 29 heart transplants were performed.

As is now well-recognized, the University of Pittsburgh has an unusually deep commitment to organ transplants of all types (kidneys, hearts, livers, heart-lung). The commitment predated the initiation of the National Heart Transplantation Study. On February 24, 1981, for example, Dr. Henry Bahnson described the evolution of the Pittsburgh program as follows:

> Dr. Thomas Starzl, formerly of Denver and one of the world's foremost leaders in transplantation joined our faculty on January 1, 1981, bringing with him funded grants, referred patients, a team of faculty, residents, and fellows, and an inside track with the Sandoz Company on Cyclosporin A for other organs. Transplantation biology has long been an important interest of many of our faculty and renal transplantation and organ procurement programs have been firmly established under Dr. Thomas Hakala. Our early efforts in 1968 in cardiac transplantation were soon shelved, but we resumed clinical cardiac transplantation last June. Before Dr. Starzl's arrivel we planned to proceed at a moderate pace, but I am sure this will now be accelerated.

As it turns out, this is precisely what happened as cardiac transplant activity at Pittsburgh grew immensely.

1. PATIENT SELECTION CRITERIA

Pittsburgh, like other heart transplant programs, is highly selective in deciding who will receive a transplant. Patients are expected to meet the following patient selection criteria:

. be 55 years of age or less

- have Class IV heart status according to the New York Heart Association Classification
- have a strong will to live and the emotional stability necessary to sustain him/her through further prolonged hospitalization.
- have a spouse, family, or support person who is willing to make a long-term commitment to provide emotional and physical support prior to and after transplantation.

Patients are excluded from consideration for a heart transplant if they manifest any of the following absolute or conditional contraindications. They are as follows:

- Absolute
  - The patient has high pulmonary vascular resistance
  - The patient currently has an infection.
- Conditional
  - There is evidence of other non-cardiac systemic disease which would limit the potential benefit of the transplant procedure.
  - The patient has had a recent cardiac catheterization. For heart transplant candidates, pulmonary vascular resistance above 6 Wood units which is unresponsive to vasodialating agents is associated with a poor perioperative outcome.
  - The patient is an insulin-requiring diabetic. This is a general contraindication because of steroid requirements post-operatively.
  - The heart transplant candidate had a recent pulmonary embolism and a period of six weeks must pass to lessen the risk of post-operative lung infection.
  - The patient is grossly obese.

2. TRANSPLANT TEAM MEMBERS

Numerous individuals are on or associated with the cardiac transplant team at Pittsburgh. Arranged according to department, they are as follows:

- Surgery
  - Henry T. Bahnson, M.D.
  - Bartley P. Griffith, M.D.
  - Robert Hardesty, M.D.
  - Shunzaburo Iwatsuki, M.D.
  - Thomas E. Starzl, M.D.
- Pathology
  - Thomas J. Gill, III, M.D.
  - Martin Ho, M.D.
  - Bruce J. Rubin, M.D.
  - Ajit Sanghui, M.D.
- Anesthesiology
  - Ake N.A. Grenuik, M.D.
  - Peter M. Winter, M.D.
- Cardiology
  - James A. Shawer, M.D.
- Medicine
  - Gerald J. Levey, M.D.
  - Mark E. Thompson, M.D.

3. PATIENT CONSENT FORMS

Prior to cardiac transplantation, all potential recipients are required to sign a consent form indicating that they are aware of

what a heart transplant involves. A copy of the patient consent form is attached here as Appendix 8-E

4. EQUIPMENT

The University of Pittsburgh team has provided a detailed list of the equipment, facilities, supplies, and personnel required to undertake a heart transplant procedure. This list has been divided into operating room requirements and preoperative and postoperative care requirements.

a. Operating Room

Facilities

1	Operating Room

Equipment

1	Operating Table
1	Heart Lung Machine
1	Coronary Perfusion Pump
1	Balloon Pump
1	Heater-Cooler Unit
1	Cautery Machine
1	Hypothermia Blanket Machine
1	Cardiac Monitoring System
1	Defibrillator/Crash Cart
1	Codman Sternal Saw
1	Bat-Wing Frame
1	Anesthesia Gas Machine
1	Mass Spectometry Machine plus ancillary components
1	Cerebral function monitor
3	IMED infusion pumps
1	Cardiac output computer
1	Fluroscope with C-arm
3	Transducers
1	Automatic Blood Pressure Monitor
2	Blood Warmers
2	Supply Carts

Staffing

1	Scrub Nurse
1	Circulating Nurse
2	Perfusionists
1	Staff Anesthesiologist
1	Cardiac Anesthesia fellow or 1 C.R.N.A.
1	Cardiac Surgeon
1	Chief Resident
1	Junior Resident

2 F.T.E. Registered Nurses staffed 5:00 p.m. - 7:00 a.m. for emergency cases

b. Pre-operative and Post-operative Care

Facilities

1 Private Room - Surgical Intensive Care Unit
1 Private Room - Coronary Care Unit
1 Private Room - Unit 74 (2 beds occasionally)

Equipment

Surgical Intensive Care Unit:

1 I.C.U. Bed
1 EKG Machine
1 Arrhythmia Machine
3 Pressure Cardules
3 Transducers
1 Respirator
1 Defibrillator/Crash Cart
Chest Tube Strippers
1 Pacemaker
3 Tyco Pumps
1 Arrest Board
2 Suction Cannisters
8 IMED Infusion Pumps
8 Pressure Monitoring Kits
1 Respiratory Therapy Heart Transplant Cart
1 Overbed Table
1 Bedside stand
1 Isolation Cart

Coronary Care Unit:

1 I.C.U. Bed
1 Arrhythmia II Protector
2 Pressure Cardules
$ IMED Infusion Pumps
2 Transducers
1 Intra Aortic Balloon Pump
1 Transplant Monitor Card

Available for use:

Defibrillator/Crash Cart
EKG Machine
Wheelchair
Pacemaker
Telemetry

Unit 74:

1 EKG Monitor
Central Monitoring Equipment
1 Transplant Monitor Cart
1 Bedside Table
1 Overbed Table

1 Hospital Bed
Telemetry

Available for use:
Defibrillator/Crash Cart
EKG Machine
Pacemaker

Staffing (per case per 24 hour period)
Surgical Intensive Care Unit:
3 F.T.E. Registered Nurses
.75 F.T.E. Nurse Aide
Portions of the following:
Respiratory Therapists
Social Workers
Unit Clerks
ICU Lab

Coronary Care Unit
1.5 F.T.E. Registered Nurses
Portions of the following:
Nurse Aides
Unit Clerk
Respiratory Therapists
Social Workers

Unit 74
For the first 24 hours, 3 F.T.E. Registered Nurses
Each 24 hours thereafter, .5 F.T.E. Registered Nurses
Portions of the following:
Nurse Aides
Unit Clerk
Social Service
Respiratory Therapy
Monitor Nurse
Psychiatric Liason
Housekeeping (special cleanings)

5. NUMBER OF TRANSPLANTS

As noted above, the University of Pittsburgh has increased its level of heart transplant activity over the past three years. The Pittsburgh team now averages over two procedures per month. Table 8-6 shows a yearly breakdown of the number of procedures performed.

6. TRANSPLANT PROTOCOL

The University of Pittsburgh team did not provide a detailed description of their transplant protocol, although their protocol has been described briefly in several publications.

Table 8-6
Number of Heart Transplants By Year At The
University of Pittsburgh

YEAR	NUMBER OF PROCEDURES
1980	3
1981	14
1982	22
1983	29

7. NATIONAL HEART TRANSPLANTATION STUDY DATA COLLECTION

Many staff members at the University of Pittsburgh graciously assisted with the data collection. Those persons who assisted with data collection are as follows:

- Toni Talarico
- Richard O'Brien
- Marianne Haramic
- Ann Lee, MSN (on-site project coordinator)
- Henry Rakov
- Robert L. Hardesty, M.D. (on-site principal investigator)
- Henry T. Bahnson, M.D.

G. STANFORD UNIVERSITY MEDICAL CENTER

A continuously active program in clinical heart transplantation was initiated at Stanford University Medical Center in January, 1968. During the first program year, ten transplant procedures in nine recipients were performed. The first heart transplant at Stanford was performed on January 6, 1968 in a 54 year-old man with cardiomyopathy; the recipient died on the 15th postoperative day of gastrointestinal bleeding and gram negative sepsis. The second recipient in the Stanford series, a 40 year-old man, received a transplanted heart on May 1, 1968, and died three days later of hypoxemia. Over the ensuing eight years the annual number of transplant procedures increased steadily to a target plateau of slightly more than two transplant procedures per month. This number has now increased to nearly three transplants per month. The Stanford team also performs heart-lung

transplants, and continues to be the most active heart transplant program in the world.

1. PATIENT SELECTION CRITERIA

Stanford considers patients eligible for heart transplants if they meet the following requirements.

- Inclusion

  . less than 55 years old
  . functional Class IV (NYHA)
  . poor prognosis for six-month survival
  . would benefit health-wise from transplant
  . emotionally stable
  . strong desire to live
  . long term commitment from family or campanion
  . strong supportive family

- Exclusions. At Stanford, patients who have any of the contraindications listed below are usually rejected as candidates for heart transplantation.

  . severe pulmonary hypertension, as reflected by calculated pulmonary vascular resistance above the range of 4-6 Wood units if unresponsive to an intravenous infusion of a vasodilator such as nitroprusside
  . severe, irreversible hepatic or renal dysfunction, the etiology of which is considered separate from cardiac failure
  . any active systemic infection
  . any separate systemic illness considered likely to limit or preclude survival and rehabilitation after cardiac transplantation

- recent and unresolved pulmonary infarction
- diabetes mellitus requiring insulin for control
- severe peripheral or cerebrovascular disease
- systemic disease (i.e., severe peripheral vascular disease, insulin-requiring diabetes, malignancy)
- moderate to severe prerenal azotemia and/or hepatic abnormalities (may be accepted if mild to moderate in severity and secondary to right heart failure)
- active peptic ulcer disease
- history of a behavior pattern (such as drug or alcohol abuse), or psychiatric illness considered sufficiently severe to interfere with compliance of lifelong medical regimen

2. TRANSPLANT TEAM MEMBERS

Primary members of the Stanford cardiac transplant team are listed below. It should be noted that representatives of other medical specialties, such as immunology, infectious disease, and neurology are always available to the team as consultants.

- Surgery
  - Dr. Edward B. Stinson
  - Dr. Norman E. Shumway
  - Dr. Philip E. Oyer
  - Dr. John Baldwin
  - Dr. Stuart W. Jamieson
  - Joan Miller, R.N., Transplant Nurse/Coordinator
  - Patricia Gamberg, R.N., Transplant Nurse/Coordinator

- Cardiology
  - Dr. John S. Schroeder
  - Dr. Sharon A. Hunt
  - Dr. Mark G. Perlroth
- Pathology
  - Dr. Margaret A. Billingham
- Social Services
  - Mary Burge, MSW

3. PATIENT CONSENT FORMS

The Stanford group requires patients to sign a consent form indicating that they are knowledgeable about heart transplantation and are aware of the risks involved. A copy of the consent form is attached here as Appendix 8-F.

4. EQUIPMENT

A list of equipoment and supplies for cardiac transplantation was not provided to us by the Stanford team.

5. NUMBER OF HEART TRANSPLANTS BY YEAR

As noted in the introduction to this description of the Stanford University cardiac transplant program, there has been a variable increase in the number of transplants performed, particularly since 1978, with the most marked increase occurring in 1983. Table 8-7 shows the distribution of transplants by year.

6. TRANSPLANT PROTOCOL

In 1960, Lower and Shumway described the key technical aspects of successful orthotopic cardiac transplantation. The operative procedure developed in the laboratory was translated

Table 8-7
Number of Heart Transplants At Stanford By Year

YEAR	NUMBER OF PROCEDURES*
1968	10
1969	9
1970	8
1971	12
1972	14
1973	15
1974	15
1975	19
1976	21
1977	20
1978	31
1979	25
1980	22
1981	25
1982	28
1983	39

*Excludes heart-lung transplants.

virtually intact into the clinical setting and remains almost unchanged from its original description. The procedures for removing the donor heart and implanting it in the recipient are described here in detail.

a. Operative Procedure. The donor heart is excised through a midline sternotomy incision after intrapericardial dissection of the superior and inferior venae cavae, the ascending aorta, and the main pulmonary artery at its bifurcation. Upon completion of the preparatory dissection, heparin is administered intravenously to the donor heart in a dose of 300 units/kg. The aorta is clamped, and the heart is then covered with cardioplegic solution. The superior vena cava is doubly ligated and divided immediately below the entrance of the azygos vein. The inferior vena cava is also doubly ligated and divided, thus maintaining a relatively bloodless field for subsequent exposure. The aorta is then transected at the origin of the innominate rtery and the pulmonary artery at its bifurcation. The heart is then elevated out of the pericardium and the pulmonary veins are divided individually at the level of their pericardial reflections. The donor heart is then immediately immersed in saline at 3-4^{C} and transferred to the recipient's operating room.

Cannulation of the recipient for cardiopulmonary bypass is similar to standard techniques for most open-cardiac surgical procedures. The arterial cannula is inserted as distally as possible in the ascending aorta. Peripheral cannulation of the femoral artery was performed in the first 5 cases in the Stanford series, but was subsequently abandoned because of a high rate of local complications, such as lymphocele formation and infection. The atrial cannulae are

both placed in a lateral position in the high right atrium near the junction of the superior vena cava and right atrium. After institution of cardiopulmonary bypass and exclusion of the atrial cannula with snares placed around the superior and inferior venae cavae, the ascending aorta is crossclamped and both great vessels are then divided at the level of the commissures of the semilunar valve. The aorta and main pulmonary artery are separated by division of the visceral pericardium to provide maximum exposure and mobility. The atria are transected immediately below the atrioventricular grooves, but posterior to the level of the atrial appendages, since these structures constitute potential sites of postoperative thrombus formation.

Implantation of the graft begins with the left atrium. The donor left atrium is opened by major connecting incisions through the pulmonary veins. The left atrial anastomosis is then begun with placement of one end of a 54-inch 3-0 polypropylene suture at the entrance of the recipient's left superior pulmonary vein and the second limb of the suture in the base of the donor heart's left atrial appendage. A running suture line is then placed on the inside and carried along the roof of the left atrium and then down the interatrial septum to join the first limb of the suture. As soon as feasible, continuous pericardial lavage with cold saline, $3\text{-}4^{C}$, is initiated during the left atrial anastomosis in order to maintain myocardial hypothermia. The donor right atrium is then opened by an incision extending from the orifice of the inferior vena cava upward in a curvilinear fashion into the base of the right atrial appendate. This technical modification, first described by Barnard, removes the donor

sinoatrial node from proximity or incorporation in the suture line and, furthermore, preserves two of the major internodal pathways that have been described by James. The sinus rhythm of nearly all patients, therefore, remains normal postoperatively. After the donor right atrium is incised, the tricuspid apparatus is inspected and a right ventricular endomyocardial biopsy is removed to serve as a control for subsequent biopsies of the graft. Anastomosis of the right atrial walls is begun at the lower end of the interatrial septum, using a second 54-in. 3-0 polypropylene suture. This is first advanced inferiorly around the orifice of the inferior vena cava and then upward along the anterolateral border of the right atrium to approximately its midportion. The second half of the suture is then carried up the interatrial septum, along the superior margin of the right atrium, and then down the lateral border to the point of termination of the first limb of the suture.

The left atrial appendage is then cannulated with an additional line for infusion of cold saline in order to induce further cooling of the left ventricle during the aortic anastomosis as well as to displace air from the left atrium and ventricle. The donor and recipient aortas are joined with a 4-0 polypropylenee suture, sewing the back wall in a running manner from the inside and completing the anterior aspect from the outside. Immediately prior to completion of the aortic anastomosis, additional attempts are made to displace air trapped in the left-sided cardiac chambers by manual manipulation of the heart and inflation of the lungs. After removal of the aortic crossclamp, the cold saline infusion line in the left atrial appendage is removed. The pulmonary anastomosis is then completed in a similar

manner. In most cases, spontaneous defibrillation of the heart occurs; if not, defibrillation is accomplished with countershock. A needle vent site is placed in the ascending aorta for further evacuation of air. After an appropriate period of continued cardiopulmonary bypass support for complete resuscitation of the graft, cardiopulmonary bypass is discontinued after initiation of isoproterenol infusion at a rate of 1-2 U/minute. The rate of infusion of isoproterenol is titrated to increase heart rate to approximately 100 beats/minute; this chronotopic effect, as well as the inotropic effect of isoproterenol, significantly increases the output of the donor heart. Two temporary pacing wires are placed in the donor right atrium; these are subsequently used for recording daily electromyograms for measurement of electrocardiographic voltage, as well as for atrial pacing if necessary.

b. Initial Postoperative Care. Upon conclusion of operation, a urinary drainage catheter is inserted. The patient is then transferred to a total reverse-isolation environment in the Intensive Care Unit. Immediate postoperative care differs little from that received by the routine cardiac surgical patient, except for institution of immunosuppression and reverse-isolation techniques. Ventilatory support with a mechanical respirator is provided for approximately 24 hours; extubation is accomplished as soon as possible. Early postoperative complications encountered in the Stanford series have been similar to those observed in severely ill patients undergoing standard cardiac surgical procedures. Most recipients exhibit reversible, mild deterioration in renal and hepatic function as determined by indirect indices; such abnormalities are

superimposed upon secondary organ failure prior to transplantation, and under current immunosuppressive regimens, made worse by cyclosporine therapy. Most recipients remain in the Intensive Care Unit for approximately 2 weeks, during which time meticulous surveillance for evidence of impending graft rejection and infectious complications of immunosuppression is maintained. Thereafter, patients are transferred to a less restricted area for an additional 2 weeks prior to discharge.

7. NATIONAL HEART TRANSPLANTATION STUDY DATA COLLECTION

Several people from the Stanford program very ably assisted with the collection of data for the study. Given the number of transplants performed at Stanford, this was a massive, time-consuming effort. A study such as this would hardly have been possible without the dedicated efforts of the following people:

- Patricia Gamberg, R.N. (on-site project coordinator)
- Polly Worrell-Uphoff
- Leslie Sullivan
- Martha Bott
- Nancy Braun
- Geri Derby, R.N.
- Lois Takaoka
- Stuart W. Jamieson, M.D. (on-site principal investigator)
- Philip Oyer, M.D.

H. CONCLUSION

This chapter has provided a rather detailed description of the six heart transplant centers that participated in the National Heart

Transplantation Study. As noted at the outset of the chapter, there are many similarities among the programs, particularly with respect to patient selection criteria and transplant protocols. Most programs have chosen to emulate the Stanford program that has really pioneered heart transplant surgery and patient management. Despite the similarities, there are some unique features associated with the various programs. Some of these features are apparent from the descriptions provided here. Interestingly, none of the programs has chosen to specialize in a particular area such as pediatric heart transplantation or heterotopic as opposed to orthotopic heart transplantation. Perhaps in the future we will begin to see a trend toward specialization.

The remarkable similarity across heart transplant programs has certainly facilitated data analysis as the unique features of the various programs are unlikely to have a direct effect on patient outcomes. Thus, while a "center effect" may contribute to differences in patient experiences, it is doubtful that such an effect is detectable statistically, although several of the chapters that follow attempt to isolate a center effect.

Throughout this report we have emphasized the cooperative spirit that prevailed at each heart transplant center that participated in the National Heart Transplantation Study. It is, once again, appropriate to underscore the nearly heroic efforts that all members of the transplant centers made to meet various project deadlines. There were the inevitable delays but they were not intended to subvert the study in any way. More often than not, the delays were due to team members trying to insure the exactness of the data we had

requested. Indeed, the National Heart Transplantation Study was a collaborative effort in every possible way. For this the National Heart Transplantation Study team is very grateful. Hopefully, at some point in the future we will be able to return the favors of our colleagues.

APPENDIX 8-A

UNIVERSITY OF ARIZONA
PATIENT CONSENT FORMS

AUTHORIZATION FOR AND CONSENT
TO HUMAN HEART TRANSPLANTATION

LOCATION_____ DATE_____

PATIENT NAME _____

Date:_____ Time: _____ PATIENT NUMBER _____

Purpose: To prolong human life in patients with terminal heart disease.

The purpose of this project is to select patients with terminal heart disease who would be good heart transplant recipients. This will be done through cardiac catheterization (explanation below). After the patient receives a heart transplant, he will be treated with medications to prevent rejection. After a 3-6 weeks hospitalization he will be discharged from the hospital and followed closely as an out-patient.

Explanation of Procedures

1. Cardiac Catheterization

Cardiac catheterization means placing a catheter or plastic tubing into the heart for the measurement of pressures and for viewing the heart under the x-ray machine. This is the initial procedure in evaluating patients suspected of having potentially fatal heart disease.

2. Other procedures

Blood tests, removing approximately one ounce of blood, an electrocardiogram and a chest x-ray, as well as a complete medical and physical examination will be carried out.

3. Guidelines for recipient selection:

The following are rough guidelines for selection of patients for heart transplantation.

(1) The patient must be felt to have terminal heart disease for which there is no further medical or surgical therapy available.
(2) He must not have diabetes mellitus.

(3) He must not have had recent blood clots in the lungs.

(4) He must not have high blood pressure in the lungs.

4. Heart Transplantation

Heart transplantation is a surgical procedure carried out while the patient is on the heart-lung machine. His own heart is removed and replaced in exactly the same position with a new and healthy heart from a heart donor. The heart donor is a patient who has been declared dead by reason of irreversible or permanent brain damage. The operation takes two-three hours. Afterwards, the patient is treated with medications including methylprednisolone, prednisone, azathioprine (cyclosporine or/imuran) by mouth; antithymocyte globulin, to be given by injection according to tendency for rejection. Other lesser medications include mycostain vaginal suppositories, which are sucked and swallowed three times per day, special mouth washes with antiiotics, antiacids such as Maalox, diuretics or water pills to reduce fluid contents in the body, and potassium chloride to replenish the body's potassium supply.

There are several side effects from these medications. The steroid medications (including methylprednisolone and prednisone) as well as azathioprine and antithymocyte globulin all reduce the body's ability to fight infection. Therefore, the risk of infection while taking these medications is increased. The physician's responsibility is to reduce the dose of these medications to the lowest level at which he can prevent rejection of the transplanted heart from occurring, thereby reducing to the lowest risk the possibility of infection. There are several other side effects of the medical treatment of rejection, however, if rejection is allowed to occur, the heart which has been transplanted will die and the patient will be lost. The antithymocyte globulin which is injected causes a painful sensation similar to a bee sting and may cause a moderate amount of swelling and redness in the site of the injection which is usually the front part of the thigh. Aside from inflammation resulting at the site of the injection, there have been no major consequences from this medication. The steroid medications (including methylprednisolone and prednisone) also have other side effects such as fluid accumulation in

the body, salt accumulation, a tendency for the face to become round in appearance, a tendency for the accumulation of body fat deposits on the trunk, a tendency for the bones to become less heavily calcified and somewhat weaker, a tendency for the skin to thin out and a tendency for increased risk for stomach or small intestinal ulceration. The azathioprine or imuran which is also one of the medications to prevent rejection can cause decrease in the cell production in the bone marrow and can cause inflammation in the liver. Imuran is only used when cyclosporine is contraindicated. Cyclosporine is an antirejection medication taken orally. It can be toxic to the kidneys which causes hypertension (or high blood pressure). The kidney function is followed closely by the physicians and blood levels are drawn daily while in the hospital. Cyclosporine also has a low incidence of lymphoma, a form of cancer.

In addition to taking medications to prevent rejection, patients have blood drawn daily (approximately 1 tablespoon), chest X-rays daily for the first two months, twice daily electrocardiograms and weekly heart biopsies. The heart biopsy is a technique which is accomplished by placing a biopsy forcep through the neck vein (jugular) on the right side. The forcep is passed into the heart using x-ray fluoroscopic visualization to make sure of its position. A small piece of heart tissue approximately 1/8 of an inch in diameter is then removed from the heart. The risk of this technique is very small and the procedure is done with a local anesthestic and can be completed within a 20 minute time period.

Risks of the Procedure

Survival following heart transplantation is approximately 70% for the first year followed by a drop-off of survival of approximately 5% per year in the ensuing years. Over half of the deaths occur from infection, slightly less than half occur from complications of rejection of the transplanted heart and a very small number have occurred from other causes. Infections are treated vigorously with antibiotics, and rejection is treated with the medications noted above.

Physical and psychological changes after heart transplantation include a sense of well-being, increased appetite, increased ability to exercise, and a tremendous feeling of energy. Sometimes this high period is followed by a low period of depression.

Heart transplant patients must develop a sense of self-preservation which accompanies all of their actions including: exercising, eating, sleeping and generally taking care of themselves in a much stricter way than normal people. The psychological effects of heart transplantation and the changes of a patient's exercise ability changes his relationship to his family and those who are close to him. Occasionally there is difficulty in making this adjustment, but usually it works out well.

My signature below is my acknowledgment that:

(1) I have read and agreed to the foregoing.

(2) The nature, demand, risks and benefits of the project have been explained to me.

(3) I understand that I may ask questions and that I am free to withdraw from the project at any time without incurring ill will.

(4) I hereby give my authorization and consent to heart transplantation as described above.

Date of Original consent_____Date of Reaffirmation of Consent_____

Patient	Patient
Witness	Patient
Physician	Physician
Complete below if patient is minor or can't sign	
Reason	Reason
Relation to Patient	Relation to Patient

APPENDIX 8-B

COLUMBIA-PRESBYTERIAN MEDICAL CENTER
PATIENT CONSENT FORM

THE PRESBYTERIAN HOSPITAL
in the City of New York
at
Columbia-Presbyterian Medical Center

Name_____Age____

Unit No. _____

Location _____

Informed Consent for Surgical Operation,
Diagnostic and Other Therapeutic Procedures
and for the Administration of Anesthesia

I give permission for the surgical operation, diagnostic or therapeutic procedures listed below and/or the administration of anesthesia and/or blood transfusions upon myself or the patient named above.

List of Procedures:_____

_____

_____

I have been advised that the procedures will be performed by Dr. _____ and his assistants. I request and consent to these procedures and other procedures which are deemed advisable by my physicians during the course of treatment. Any organs or tissues which are surgically removed may be examined and retained by the Hospital for5 medical, scientific or educational purposes and may be disposed of according to customary practices.

Restrictions:_____

_____
(State Restrictions or None)

The nature and purpose of the procedures, the expected discomforts, risks, complications and benefits and the alternative treatments, if any, have been fully explained to me. I acknowledge that no guarantees or assurances have been made to me concerning the results intended from the procedures. I have been given the opportunity to ask questions and all my questions have been answered fully and satisfactorily by:

Dr. _____
Signature

Witness: _____

Signed:_____(Patient)

Date: _____

When patient is a minor or incompetent to give consent:

Witness: _____

Signed:_____
Signature of person authorized
to consent for patient
Relationship to patient

_____

Date:_____

APPENDIX 8-C

MEDICAL COLLEGE OF VIRGINIA
PATIENT CONSENT FORM

CLINICAL RESEARCH CENTER
MEDICAL COLLEGE OF VIRGINIA HOSPITAL
RICHMOND, VIRGINIA

CONSENT FORM FOR CARDIAC TRANSPLANTATION

Name _____

MCV # _____

Before entering the Clinical Research Center, I wish to state that the risks and possible benefits of cardiac transplantation have been explained to me. I understand that my cardiac disease is severe and that my outlook for survival with conventional treatment is very limited. It is for this reason that the procedure of cardiac transplantation has been recommended and the physicians of the Medical College of Virginia will evaluate my suitability as a transplantation candidate. If they find my case suitable, I will agree to undergo this procedure and understand that it is of an experimental nature and entails serious risks of complication such as infection or transplant rejection from which I may not survive.

I give permission to the doctors of the Medical College of Virginia Hospital and any assistants they may cll to their aid to perform all necessary tests to evaluate my case and to perform cardiac transplantation if this is judged to be my only hope of survival.

I also give permission to the Medical College of Virginia to make photographic or other illustrations as deemed advisable for diagnostic purposes and/or to enhance the medical record. I further authorize the use of such illustrations for scientific or teaching purposes.

I further recognize my right to withdraw at any time from this investigational study and that conventional medical therapy will be administered in such a circumstance.

_____ _____

Investigator's Signature Patient's Signature

I was present when the physician explained the procedures and in my opinion the patient understood the factors involved.

_____

Witness

_____

Date

APPENDIX 8-D
UNIVERSITY OF MINNESOTA AUTHORIZATION FOR CARDIAC TRANSPLANTATION PATIENT CONSENT FORM

AUTHORIZATION FOR CARDIAC TRANSPLANTATION

Date:_____

Time:_____

I, _____, willingly agree to permit Dr. Robert Anderson, Dr. Ernesto Molina, Dr. R. Morton Bolman (and/or whom each may designate) to do a heart transplant upon me. Dr. _____ has alerted me to potential complications and discussed both the benefits and relative alternative methods of treatment which could be used. I have been informed that my heart is so damaged by disease as to threaten my life and that in my present condition my outlook for prolonged survival as well as the quality of life is extremely poor. I have also been informed that other regularly available and potentially beneficial alternative forms of treatment have already been tried without achieving an acceptable degree of relief. I have been informed of the known statistics applicable to heart transplant recipients.

I am aware that if I accept heart transplantation I will be required to take medications on a daily basis for the rest of my life if my heart is to continue to function as well as it can. I am aware that these medications just as with the heart transplant procedure can lead to serious complications. These serious events can include an induced malfunction of the heart as a consequence of the body's natural reaction against the graft. This event could be characterized by a variety of signs of symptoms or abnormal laboratory tests which physicians identify with rejection of the heart. Should this occur, I may have to be hospitalized. For a rejection episode I will have to be treated with an increased amount in strength of those medicines used to prevent graft rejection.

From time to time, there could also be potentially life threatening infections requiring treatment. I have been informed that infections due to the medication used to prevent a rejection are common complications for persons receiving heart transplants. These include viral, fungal and bacterial infections. If such an infection

develops, I realize I probably will have to return to the hospital to receive proper treatment.

I might also develop unattractive alterations in my appearance from those medicines I must take to control the rejction in my body to this new heart. I also realize that I will be required to return to the hospital and to my family physician for frequent follow-up examinations. For the former, I should plan on returning to this hospital at least two times per week for the first month and less frequently thereafter. I realize that I will have to be checked by my family physician at least once per month for the rest of my life. Should a significant abnormality be found at the clinic visit I am aware that hospitalization could be required to protect my health. During my clinical visit follow-up, I realize that I may have to have blood tests, electrocardiograms, or any other applicable test the staff believes necessary in properly carying for me. At any hospitalization a biopsy of my heart may be required. I have been informed that following transplantation a biopsy of my heart every six to ten days for the first month or two after transplantation is in my best interests. Later, I will need a similar biopsy at least every e months. This will be done essentially as described in that consent form.

I have been able to ask any and all questions that I have wished in regarding heart transplantations, its techniques, complications and alternate therapy. I believe, too, that each question has been answered to my satisfaction and with my understanding.

No other promises have been made to me regarding either short or long term success or benefits of my heart transplant or of the procedure in general. I understand that I may withdraw from this program at any time prior to heart transplantation without its influencing the quality of choice of subsequent medical or surgical therapy.

Witness:_____

Signed:_____

Parent or Guardian:_____ Date:_____

(If patient is a minor)

APPENDIX 8-E

UNIVERSITY OF PITTSBURGH
PATIENT CONSENT FORMS

CONSENT TO ACT AS A SUBJECT IN AN EXPERIMENTAL STUDY

TITLE: Cardiac Transplantation Using treatment with Cyclosporin A Plus Prednisone

INVESTIGATORS:

Henry T. Bahnson, M.D.
Professor and Chairman
Department of Surgery
University of Pittsburgh
School of Medicine
(412) 624-2677

Thomas E. Starzl, M.D.
Professor of Surgery
University of Pittsburgh
School of Medicine
(412) 624-1042

Robert L. Hardesty, M.D.
Associate Professor of Surgery
University of Pittsburgh
School of Medicine
(412) 624-2677

Shunzaburo Iwatsuki, M.D.
Assistant Professor of Surgery
University of Pittsburgh
School of Medicine
(412) 624-1042

SOURCE OF SUPPORT: Sandoz, Inc.

DESCRIPTION: Dr. Bahnson and his co-workers have undertaken a study to establish a safe, reliable method of cardiac replacement and subsequent protection against rejection of the transplanted heart.

The operation will remove my diseased heart when necessary and replace it with a normal heart donated by a brain dead person. After the heart transplantation, I will have to take a new drug, Cyclosporin A, together with prednisone as long as necessary, usually for life. The experimental part of the study is to see if this new drug plus prednisone will protect my new heart from rejection.

Heart transplantation has been tried on humans since 1963 and significant technical progress has been made. Using standard treatment (azathioprine and prednisone and antilymphocyte globulin) to prevent rejection, the longest survival has been over 10 years. The overall survival for one year in the largest series (Stanford) was about 60%.

A new drug, Cyclosporine A, may prevent the rejection of my new heart. This drug is an extract of two fungi discovered in 1976. This drug has been used in humans since 1978, and members of the Pittsburgh team have been testing it in human kidney and liver transplantations since 1979. Their early experience, as well as that of others, showed that Cyclosporine A is a relatively safe, reliable and powerful drug against rejection, but that more has to be learned about the drug. Whether or not this drug is superior to other treatment for long-term use has to be determined. This drug is given by injection into the muscle or by mouth daily, probably for life.

RISKS AND BENEFITS: The benefit to me might be prolonged survival after cardiac transplantation with no greater and possibly less risk of life-threatening infection than is possible with conventional anti-rejection drugs. It is already known that much smaller amounts of prednisone can be used compared to that required if azathioprine (Imuran) is used instead of Cyclosporine A.

The known side effects of Cyclosporin A are: (1) possible injury to the liver, (2) possible injury to the kidney, (3) overgrowth of hair, (4) overgrowth of the gums, (f) flushing, (6) tingling, (7) trembling of hands. These symptoms can be decreased or eliminated by reducing the dose or by withdrawing the drug. It is thought that withdrawing the drug will increase the risk of rejection of the transplanted heart. Cancer (lymphoma: white blood cell cancer) has developed in a few patients under Cyclosporin A therapy, but a similar increased incidence of cancer has been well known under standard therapy used against rejection.

ALTERNATIVE TREATMENTS: I understand that conventional therapy to prevent rejection has been standardized with a combination of azathioprine and prednisone to which antilymphocytic globulin (ALB) is often added. The results have not been completely satisfactory. With these agents the one-year survival has been about 60%. I have been told that I may be treated with azathioprine and prednisone (with or without ALG) if that is my wish.

NEW INFORMATION: If new information, either good or bad, about Cyclosporine A develops during the course of this study, I will be so informed. Also, if any other new effective treatment for my condition is discovered, Dr. Bahnson or his co-workers will tell me.

COST AND PAYMENTS: Cyclosporine A will be provided free of charge. Other medications and all laboratory, physician or hospital costs will be charged to me in the same fashion as if I were not part of this study.

CONFIDENTIALITY: I understand that any information about me obtained from this research including history, laboratory data, findings on physical examination, biopsy, or surgery will be kept strictly confidential. I do understand that my research records, just like hospital records, may be subpoenaed by court order. I consent to the publication of study results so long as the information is anonymous and/or disguised so that identification cannot be made.

RIGHT TO WITHDRAW: I understand that I am free to refuse to participate in this study or to withdraw at any time and that my decision will not adversely affect my care at this institution or cause a loss of benefits to which I might be otherwise entitled.

_____

PATIENT'S INITIALS

COMPENSATION FOR ILLNESS OR INJURY: I understand that in the event of a physical injury or illness resulting from the reseach procedures no monetary compensation will be made, but any immediate emergency medical treatment which may be necessary will be made available to me without charge.

VOLUNTARY CONSENT. I certify that I have read the preceding or it has been read to me and that I understand its contents. Any questions I have pertaining to the preceding have been and will be answered by Dr. _____. A copy of this consent form will be given to me. My signature below means that I have freely agreed to participate in this experimental study.

_____ _____

DATE PATIENT SIGNATURE

_____

WITNESS

For Minors:

I, _____, have also read the preceding and agree to the participation of my child.

_____ _____

DATE SIGNATURE

_____

WITNESS

APPENDIX 8-F

STANFORD UNIVERSITY MEDICAL CENTER
PATIENT CONSENT FORM

STANFORD UNIVERSITY HOSPITAL
STANFORD MEDICAL CENTER
STANFORD, CALIFORNIA 94305
CONSENT OF RECIPIENT FOR TRANSPLANTATION

Date_____ Time _____

Experimental Subjects Bill of Rights: Persons who paricipate in experimental medical procedures are entitled to certain rights. These rights include but are not limited to the subject's right to: Be informed on the nature and purpose of the experiment; be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized; be given a description of any attendant discomforts and risks reasonably to be expected; be given a explanation of any benefits to the subject reasonably to be expected; be given a disclosure of any appropriate alternatives, drugs, or devices that might be advantageous to the subject, the relative risks and benefits; be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise; be given an opportunity to ask any questions concerning the experiment or the procedures involved, be instructed that consent to participate in the experimental procedure may be withdrawn at any time prior to transplantation without prejudice to the subject's medical care; be given a copy of the signed and dated consent form; and be given the opportunity to consent to or not to consent to the medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

1. I hereby authorize Dr. _____and such assistants as may be selected by him to perform a _____transplantation upon me. I understand that this may necessitate removal of my _____now or at a later date. I recognize that during the operation unforeseen conditions may necessitate additional or different procedures and accordingly I further authorize and request the above-named surgeon, his assistants, or his designees to perform such procedures that are or become in his professional judgment, necessary or desirable. The authority granted hereunder shall extend to conditions that are not known to Dr. _____ at the time the operation is commenced.

---

2. I hereby authorize and direct the above-named surgeon and/or his associates or assistants to provide such additional services for me as he or they may deem reasonable and necessary including, but not limited to, the administration and maintenance of the anesthesia, and the performance of services involving pathology and radiology, and I hereby consent thereto.

3. I acknowledge that Dr. _____has thoroughly discussed the above-described procedure with me and that the nature and consequences of the transplantation have been fully explained to me. This explanation included discussion of the infectious, metabolic and other risks of immunosuppression, the probability of graft rejection, and its diagnosis and treatment, other potential complications, the range of possible effects on my health and well-being following the procedure, and the possibility of death. I understand that the outcome of the transplantation is not entirely predictable and that the range of expectation of survival for at least one year after transplantation at the current time is 50-60%. There has been no guarantee of any initial or continuing success.

4. I understand that the donor, or an appropriately authorized member of his/her family, has volunteered to donate his/her _____ to me and that this donation is being made without any obligation or liability of any kind or sort on my part. I hereby release said donor from any liability to me on account of any condition which may subsequently develop as a result of transplantation of his/her _____ to me.

STANFORD UNIVERSITY HOSPITAL
STANFORD MEDICAL CENTER
STANFORD, CALIFORNIA 94305
CONSENT OF RECIPIENT FOR TRANSPLANTATION

---

5. I DO_____ DO NOT _____ authorize release to the news media and scientific publications the name of _____ as the recipient in a transplantation procedure at Stanford University Hospital. Any data under the investigator's control will be disclosed in a manner that does not reveal my identify.

6. I further acknowledge that all of my questions regarding the proposed procedure have been answered to my satisfaction. Members of the transplantation team (497-5771 or 497-6141) will be glad to answer any additional questions that I may have later.

7. In the event of physical injury that arises solely out of the negligence of the Stanford University Medical Center or its staff in this study, reimbursement for expenses incurred for necessary medical treatment and hospitalization is available. For further information, please call 497-5244 or write the Medical Center Committee for the Protection of Human Subjects at 851 Welch Road, Room 115, Palo Alto, California, 94304. In addition, if you are not satisfied with the manner in which this study is being conducted, you may report any complaints to the same telephone number and address.

MY SIGNATURE INDICATES THAT I HAVE READ AND UNDERSTAND THE ABOVE INFORMATION, THAT I HAVE DISCUSSED THIS PROCEDURE WITH MEMBERS OF THE TRANSPLANTATION TEAM AND HAVE DECIDED TO PARTICIPATE ON THE BASIS OF THE INFORMATION PROVIDED. A COPY OF THIS FORM IS AVAILABLE TO ME UPON REQUEST.

Witness _____ Signed _____
(Recipient)

Witness _____

(Revised 3/23/79)

STANFORD UNIVERSITY HOSPITAL/STANFORD MEDICAL CENTER,
STANFORD, CALIFORNIA 94305
CONSENT FOR MINOR RECIPIENT FOR TRANSPLANTATION

Date:_____Time:_____

Experimental Subjects Bill of Rights: Persons who paricipate in experimental medical procedures are entitled to certain rights. These rights include but are not limited to the subject's right to: Be informed on the nature and purpose of the experiment; be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized; be given a description of any attendant discomforts and risks reasonably to be expected; be given a explanation of any benefits to the subject reasonably to be expected; be given a disclosure of any appropriate alternatives, drugs, or devices that might be advantageous to the subject, the relative risks and benefits; be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise; be given an opportunity to ask any questions concerning the experiment or the procedures involved, be instructed that consent to participate in the experimental procedure may be withdrawn at any time prior to transplantation without prejudice to the subject's medical care; be given a copy of the signed and dated consent form; and be given the opportunity to consent to or not to consent to the medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

1. I hereby authorize Dr. _____ and such assistants as may be selected by him to perform a _____ transplantation upon _____, my child who is ____ years of age. I understand that this may necessitate removal of his/her _____now or at a later date. I recognize that during the operation unforeseen conditions may necessitate additional or different procedures and accordingly I further authorize and request the above-named surgeon, his assistants, or his designees to perform such procedures that are or become, in his professional judgment, necessary or desirable. The authority granted hereunder shall extend to conditions that are not known to Dr. _____ at the time the operation is commended.

2. I hereby authorize and direct the above-named surgeon and/or his associates or assistants to provide such additional services for my child as he or they may deem reasonable and necessary including, but not limited to, the administration and maintenance of the anesthesia, and the performance of services involving pathology and radiology, and I hereby consent thereto for my child.

3. I acknowledge that Dr. _____has thoroughly discussed the above-described procedure with me and that the nature and consequences of the transplantation have been fully explained to me and my child. This explanation included discussion of the infectious, metabolic and other risks of immunosuppression, the probability of graft rejection, and its diagnosis and treatment, other potential complications, the range of possible effects on my child's health and well-being following the procedure, and the possibility of death. I understand that the outcome of the transplantation is not entirely predictable and that the range of expectation of survival for at least one year after transplantation at the current time is 50-60%. There has been no guarantee of any initial or continuing success.

4. I understand that the donor, or an appropriately authorized member of his/her family, has volunteered to donate his/her _____ to my child and that this donation is being made without any obligation or liability of any kind or sort on my or my child's part. I hereby release said donor from any liability to me or my child on account of any condition which may subsequently develop as a result of transplantation of his/her _____ to my child.

5. I DO_____ DO NOT _____ authorize release to the news media and scientific publications my name, or my child's name, as the recipient in a transplantation procedure at Stanford University Hospital. Any data under the investigator's control will be disclosed in a manner that does not reveal my identify.

6. I further acknowledge that all of my and my child's questions regarding the proposed procedure have been answered to my and my child's satisfaction.

7. I understand that I have the right to withdraw my consent at any time before the time of transplantation without prejudice to my medical care. Members of the transplantation team (497-5771 or 497-6151) will be glad to answer any additional questions that I may have later.

8. In the event of physical injury that arises solely out of the negligence of the Stanford University Medical Center or its staff in this study, reimbursement for expenses incurred for necessary medical treatment and hospitalization is available. For further information, please call 497-5244 or write the Medical Center Committee for the Protection of Human Subjects at 851 Welch Road, Room 115, Palo Alto, California, 94304. In addition, if you are not satisfied with the manner in which this study is being conducted, you may report any complaints to the same telephone number and address.

STANFORD UNIVERSITY HOSPITAL/STANFORD MEDICAL CENTER,
STANFORD, CALIFORNIA 94305
CONSENT FOR MINOR RECIPIENT FOR TRANSPLANTATION

MY SIGNATURE INDICATES THAT I HAVE READ AND UNDERSTAND THE ABOVE INFORMATION, THAT I HAVE DISCUSSED THIS PROCEDURE WITH MEMBERS OF THE TRANSPLANTATION TEAM AND HAVE DECIDED TO PARTICIPATE ON THE BASIS OF THE INFORMATION PROVIDED. A COPY OF THIS FORM IS AVAILABLE TO ME UPON REQUEST.

Witness _____ Signed _____
(Parent or Legal Guardian)

Witness _____ _____
(Parent or Legal Guardian)

Assent of Child:_____

(Revised 3/23/79)

CHAPTER 9

A DESCRIPTIVE ANALYSIS OF HEART TRANSPLANT RECIPIENTS

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A. INTRODUCTION

As described in Chapter 5, 152 living heart transplant recipients completed an extensive questionnaire on all aspects of their transplant experience. In completing the questionnaire, patients provided detailed sociodemographic data, an assessment of their quality of life, a description of their level of physical functioning and daily activities, an account of their family and social relations, an indication of both their ability to work as well as their work history, an assessment of their health status and personal adjustment, and, finally, a detailed account of the costs associated with their transplant and how their transplant was financed. In this chapter of the report some of these data are summarized, along with data from the medical and hospital records of those patients who provided consent for a review of their records. The purpose of this chapter is to provide a broad descriptive overview of heart transplant recipients. More detailed analyses of some of these data have been included in subsequent chapters.

In providing an overview such as this, there is one rather significant problem. Given the small number of living transplant recipients in the study and the U.S. as a whole, care must be taken in presenting these data to protect the anonymity of the patients. Extensive stratification of the data to smaller and smaller subgroups of patients could easily result in the identification of specific patients on the basis of their characteristics, even though the data contain no personal identifiers. Thus, all data presented here are aggregated so as not to permit the identification of patients.

This chapter has been organized according to various topics. We begin with a sociodemographic characterization of the patients, then discuss various medical considerations. We provide some insight into the family and social relationships of the patients, examine their level of self-reported personal adjustment, and then describe their health status and activity level, as well as their employment status. The chapter concludes with a discussion of their financial situation and how well they have been able to deal with the considerable financial burden imposed by heart transplantation.

Throughout the discussion that follows, the reader should not lose sight of the fact that much of the data presented here were provided by living heart transplant recipients. To some extent, we have also provided a description of deceased heart transplant recipients. Since very detailed data are not available on the deceased heart transplant recipients, this chapter has purposely been devoted primarily to a discussion of living heart transplant recipients.

B. SOCIODEMOGRAPHIC CONSIDERATIONS

1. AGE

The age distribution of the patients who completed questionnaires as part of the National Heart Transplantation Study is shown in Table 9-1. The average age of a living heart transplant recipient is 42.38 years (S.D.= 9.99). It should be noted that most heart transplant teams consider age in excess of 50 years to be a relative contraindication to heart transplantation, and age in excess of 55 years an absolute contraindication (Baumgartner et al., 1979; Pennock et al., 1982; Copeland and Stinson, 1979; Jamieson et al.,

Table 9-1
Age Distribution of Living Heart Transplant Recipients

AGE (IN YEARS)	NUMBER OF PATIENTS	PERCENT OF PATIENTS
18.00 - 19.99	1	.7
20.00 - 24.99	6	4.0
25.00 - 29.99	16	10.5
30.00 - 34.99	15	9.9
35.00 - 39.99	18	11.8
40.00 - 44.99	23	15.1
45.00 - 49.99	33	21.7
50.00 - 54.99	30	19.7
55.00 - 59.99	9	5.9
60.00 - 64.99	1	0.7

RANGE = 19.307 - 60.329
MEAN = 42.383
S.D. = 9.993
MEDIAN = 44.177

1981; Reitz and Stinson, 1982). It is noteworthy that chronological age per se is not truly the basis for exclusion, but rather the presence of comorbid conditions known to have onset by the fifth decade of life are the major source of concern. Thus, coexisting disease rather than age is really the basis for rejecting patients for heart transplantation.

2. SEX

Not surprisingly, given the higher prevalence of heart disease among men than women, particularly ischemic heart disease, 87.5 percent (133 patients) of the living heart transplant recipients are male. Only 19 of the living heart transplant recipients are female. Based on need estimates for 1980 provided in Chapter 12 for the ages 10-54 need category (see Table 12-16), we estimate that 10,249 males and 3,903 females may have benefited from a heart transplant. Given these figures, it is estimated that 72.4 percent of the heart transplant recipient pool should be male and 27.6 percent should be female. Thus, it is reasonable to conclude that males are perhaps slightly (15.1 percent) overrepresented among the living heart transplant recipients.

An analysis of the data for both living and deceased heart transplant recipients (N = 441) reveals only a slightly different distribution of patients according to sex. As shown in Table 9-2, of the 441 patients who received heart transplants at the six centers participating in the study, 85.9 percent were male. Thus, females remain underrepresented by 13.5 percent.

Table 9-2
Sex Distribution of Heart Transplant Recipients

	LIVING PATIENTS		ALL PATIENTS	
SEX	NUMBER	PERCENT	NUMBER	PERCENT
MALE	133	87.5	379	85.9
FEMALE	19	12.5	62	14.1

3. RACE

The racial distribution of patients in the study is shown in Table 9-3. Clearly, the vast majority (87.5 percent) of recipients are white. Relatively few patients are distributed over the remaining race categories. Again, using need data presented in Chapter 12, it is possible to determine if the distribution of patients is as expected. Based on the need data for 1980 presented in Chapter 12 for the ages 10-54 need category (see Table 12-16), the following racial distribution of patients would be expected: whites, 77.1 percent, blacks 21.3 percent, and "others," 1.6 percent. Thus, with respect to need, it is evident that whites are perhaps overrepresented by 10.4 percent among heart transplant recipients, blacks are under-represented by 18.0 percent, and "others" are overrepresented by 7.6 percent. An analysis of all heart transplant recipients reveals that 91.4 percent are white suggesting that whites may be overrepresented by as much as 14.3 percent.

4. MARITAL STATUS

End-stage cardiac disease like any terminal or chronic disease poses substantial problems for patients and their families. Therefore, data were obtained not only on the marital status of patients but on adjustment achieved by patients who were married and the experiences of patients who had divorced or separated subsequent to their transplant. The distribution of patients according to their marital status currently and at the time they were evaluated for a heart transplant is shown in Table 9-4. As shown in Table 9-4, the majority of patients were married. This is not surprising given the age at which patients are likely to be transplanted and the importance

Table 9-3
Racial Distribution of Heart Transplant Recipients

	LIVING PATIENTS		ALL PATIENTS	
RACE	NUMBER	PERCENT	NUMBER	PERCENT
WHITE	133	87.5	403	91.4
BLACK	5	3.3	17	3.9
OTHER	14	9.2	18	4.0
NOT KNOWN	0	0.0	3	0.7

Table 9-4
Distribution of Living Heart Transplant Recipients
According to Current Marital Status

	CURRENT[1]		AT TIME OF EVALUATION[2]	
MARITAL STATUS	NUMBER	PERCENT	NUMBER	PERCENT
MARRIED	111	73.0	314	71.2
WIDOWED	0	0.0	2	0.5
DIVORCED	14	9.2	27	6.1
SEPARATED	5	3.3	4	0.9
NEVER MARRIED	22	14.5	87	19.7
NOT KNOWN	0	0.0	7	1.6

[1]Living patients only (N = 152).

[2]All patients (N = 441).

that a supportive social environment holds in the selection of heart transplant recipients. Nineteen patients were currently separated or divorced, perhaps reflecting the nature of the transplant experience, although only 4 of the divorced patients felt that their divorce was a direct result of their need for a heart transplant. Interestingly, however, 55.5 percent of the divorced patients claimed that the heart transplant strained their marriage. Four patients had remarried since their transplant. Of the married patients, 36 or nearly one-quarter of them, felt that their heart transplant strained their marriage. Yet, when asked how understanding their spouse was about their heart condition, 89.3 percent of the married patients characterized their spouse as "very understanding," while the remaining 10.7 percent of the patients felt their spouse "could be more understanding." Only six of the married patients often felt that they have been rejected by their spouse when they are sick. Interestingly, however, of the married patients, 67.9 percent felt that their relationship to their spouse has been closer since their transplant, 21.4 percent "about the same," and 10.7 percent, "less close." Over 90 percent of the married patients were "very or somewhat satisfied" with their relationship to their spouse.

5. EDUCATION

Results of the survey revealed that living heart transplant recipients, on the whole, were well-educated. Table 9-5 shows the levels of education attained by the patients in the study. To summarize, 10.5 percent of the patients never graduated from high school, 56.6 percent had received a high school diploma, 21.7 had

Table 9-5
Levels of Education Attained By Living
Heart Transplant Recipients

YEARS OF EDUCATION	NUMBER OF PATIENTS	PERCENT OF PATIENTS
3-12	72	47.4
13-16	51	33.6
17-18	19	12.5
19 OR MORE	10	6.5

received a college or university degree, and, finally, 11.2 percent had received an advanced degree.

C. MEDICAL CONSIDERATIONS

1. LENGTH OF TIME BETWEEN DIAGNOSIS OF HEART DISEASE AND TRANSPLANTATION

As shown in Table 9-6, there is considerable variation among heart transplant recipients in terms of the length of time between the time they were first diagnosed as having heart disease and when they received their heart transplant. Although somewhat deceiving given the wide variation, the average number of years is 5.4 (S.D. = 7.5). The median length of time is 3.1. The shorter length of time for some patients undoubtedly reflects the nature of their condition. For example, viral cardiomyopathy, in the absence of transplantation, results in death in a much shorter period of time than does a condition like coronary artery disease.

2. LENGTH OF TIME SINCE TRANSPLANT

All patients were asked when they received their most recent heart transplant, since four living patients have actually had two heart transplants; that is, they have been retransplanted on one occasion. The longest living survivor received their transplant 13.85 years ago. The mean length of time since transplant is 2.99 years (S.D. - 2.80). Median length of time since transplant is 1.91 years. Table 9-7 summarizes, by number of years, the length of time patients in this study have had their transplant. As shown in this table, the majority of transplant recipients have had their transplant two years or less. Heart transplant patient survival, a more complicated matter

Table 9-6
Length of Time Since Diagnosis of Heart Disease
Among Living Heart Transplant Recipients

LENGTH OF TIME (IN YEARS)	NUMBER OF PATIENTS	PERCENT OF PATIENTS
.01 - .50	21	14.0
.51 - .99	16	10.7
1.00 - 1.99	24	16.0
2.00 - 2.99	10	6.7
3.00 - 3.99	19	12.7
4.00 - 4.99	15	10.0
5.00 - 5.99	6	4.0
6.00 - 6.99	5	3.3
7.00 - 7.99	4	2.7
8.00 - 8.99	3	2.0
9.00 - 9.99	5	3.3
10.00 - 10.99	4	2.7
11.00 - 39.78	18	12.0

RANGE = .005 to 39.778
MEAN = 5.398
S.D. = 7.525
MEDIAN = 3.087

Table 9-7
Length of Time Since Transplant For Living
Heart Transplant Recipients

LENGTH OF TIME (IN YEARS)	NUMBER OF PATIENTS	PERCENT OF PATIENTS
.01 - .50	19	12.7
.51 - .99	22	14.7
1.00 - 1.99	36	24.0
2.00 - 2.99	23	15.3
3.00 - 3.99	11	7.3
4.00 - 4.99	6	4.0
5.00 - 5.99	11	7.3
6.00 - 6.99	6	4.0
7.00 - 7.99	5	3.3
8.00 - 8.99	3	2.0
9.00 - 9.99	3	2.0
10.00 - 10.99	2	1.3
11.00 - 11.99	1	0.7
12.00 - 12.99	1	0.7
13.00 - 13.99	1	0.7

RANGE = .315 - 13.851
MEAN = 2.990
S.D. = 2.804
MEDIAN = 1.907

than length of time living heart transplant recipients have had their transplants, is analyzed and described in great detail in later chapters of this report.

3. PRIMARY DISEASE DIAGNOSIS

Based on a thorough review of medical and hospital records for those patients who provided consent, Table 9-8 shows the primary disease diagnosis for the living heart transplant recipients. Table 9-8 also shows the distribution of primary diagnoses among nonliving heart transplant recipients. Clearly, coronary artery disease and cardiomyopathy are the two leading preoperative primary diagnoses among living and deceased heart transplant recipients (Baumgartner et al., 1979; Copeland and Stinson, 1979).

4. PREOPERATIVE CONTRAINDICATIONS TO HEART TRANSPLANTATION

Table 9-9 shows the contraindications to heart transplantation that both living and deceased heart transplant recipients had preoperatively. Clearly, some heart transplant recipients exhibited contraindications to heart transplantation prior to receiving their transplant. This is likely to reflect the evolution of patient selection criteria since the first heart transplant was performed in 1967. Over time, patient selection criteria have become more restrictive and the Stanford group, in particular, attributes improved patient survival to the fact that it is more selective in who is transplanted.

5. HEART FUNCTION ACCORDING TO THE NEW YORK HEART ASSOCIATION

It is generally agreed that candidates for a heart transplant should have terminal cardiac disease with advanced functional disability and a prognosis of survival that is limited to several

Table 9-8
Primary Heart Disease Diagnosis For Living
And Deceased Heart Transplant Recipients

PRIMARY PREOPERATIVE DIAGNOSIS	PERCENT OF LIVING RECIPIENTS	PERCENT OF DECEASED RECIPIENTS
Coronary Artery Disease	37.3	51.6
Idiopathic Cardiomyopathy	50.7	39.5
Valve Disease with Cardiomyopathy	0.7	1.6
Rheumatic Valvular Disease	3.3	2.7
Congenital Heart Disease	2.7	1.2
Other	0.0	3.1
Missing Data	5.4	0.4

Table 9-9
Preoperative Contraindications to Heart Transplantation Among
Living and Deceased Heart Transplant Recipients

CONTRAINDICATIONS		LIVING RECIPIENTS[1]		DECEASED RECIPIENTS	
		NUMBER	PERCENT	NUMBER	PERCENT
19.1	SEVERE PULMONARY HYPERTENSION	0	0.0	3	1.2
19.2	IRREVERSIBLE AND SEVERE HEPATIC DYSFUNCTION	1	0.7	4	1.6
19.3	IRREVERSIBLE AND SEVERE RENAL DYSFUNCTION	1	0.7	3	1.2
19.4	ACTIVE SYSTEMIC INFECTION	0	0.0	2	0.8
19.5	OTHER SYSTEMIC DISEASE LIKELY TO LIMIT OR PRECLUDE SURVIVAL AND REHABILITATION AFTER TRANSPLANTATION	0	0.0	0	0.0
19.6	PSYCHIATRIC ILLNESS OR SEVERE BEHAVIORAL DISORDER	2	1.3	0	0.0
19.7	PHYSICAL HANDICAP	0	0.0	0	0.0
19.8	RECENT AND UNRESOLVED PULMONARY INFARCTION	1	0.7	5	2.0
19.9	INSULIN-REQUIRING DIABETES MELLITUS	0	0.0	4	1.6
19.10	SYMPTOMATIC OR DOCUMENTED SEVERE ASYMPTOMATIC PERIPHERAL OR CEREBROVASCULAR DISEASE	2	1.3	2	0.8
19.11	ACTIVE PEPTIC ULCER DISEASE	2	1.3	1	0.4
19.12	ABSENCE OF ADEQUATE EXTERNAL PSYCHOSOCIAL SUPPORT	0	0.0	3	1.2
19.13	ADVANCING AGE (UNABLE TO WITHSTAND SURGERY OR POSTOPERATIVE COMPLICATIONS)	3	2.0	2	0.8
19.14	PULMONARY VASCULAR RESISTANCE GREATER THAN EIGHT WOOD UNITS	0	0.0	1	0.4
19.15	DRUG OR ALCOHOL ADDICTION	1	0.7	6	2.4
19.16	GOOD PROGNOSIS DESPITE CARDIAC DISEASE (BETTER THAN 10-25 PERCENT LIKELIHOOD OF SURVIVING FOR 6 MONTHS)	0	0.0	6	2.4
19.17	DIABETES, NOT INSULIN-DEPENDENT	1	0.7	16	6.3
19.18	OTHER[3]	0	0.0	20	7.8

[1]N = 150

[2]N = 256

[3]Includes contraindications such as severe congestive heart failure, left ventricular aneurysm, cerebral and pulmonary embolism, seizure disorder, Gilbert's syndrome, memory loss, too young, distance to center, obesity, unable to speak English, and unability to pay.

weeks or months. In this regard, cardiologists and cardiovascular surgeons generally rate patients according to a scheme developed by the New York Heart Association (NYHA). In general patients must have Class IV heart disease. As shown in Table 9-10, not all heart transplant recipients, living or deceased, were necessarily Class IV at the time of their evaluation. The majority of the patients were, however. At least part of the variation in functional classification at time of evaluation may be a reflection of the patient's disease. For example, it is quite possible that when the patient's demise is imminent (e.g., cardiac tumor), the team may be willing to perform the procedure at a slightly earlier point in the patient's disease course in order to ensure a better outcome for the patient.

Data were also obtained on current NYHA functional status of all living heart transplant recipients. As shown in Table 9-11, there is some variation among patients in how well they are doing. Clearly the majority of patients have attained Class I functioning.

6. IMMUNOSUPPRESSION

Data were abstracted from medical records on all the immunosuppressive protocols patients have been on. Detailed attention was given to three time periods: (1) immediately following transplant surgery, (2) at the time of initial discharge, and (3) at present time or at the patient's death. Table 9-12 shows the number and percentage distribution of living heart transplant recipients according to specific drugs at each of the foregoing time periods. Table 9-13 shows the same array of data for deceased heart transplant recipients. As shown in Table 9-12, 51.4 percent of the living heart transplant recipients are currently on cyclosporine, while 14.2 percent of the

Table 9-10
NYHA Functional Classification at Time of Evaluation for
Living and Deceased Heart Transplant Recipients

CLASS			LIVING RECIPIENTS[1]		DECEASED RECIPIENTS[2]	
			NUMBER	PERCENT	NUMBER	PERCENT
CLASS	I	Patients with cardiac disease but without resulting limitations of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain.	0	0.0	1	0.4
CLASS	II	Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain.	0	0.0	1	0.4
CLASS	III	Patients with cardiac disease resulting in marked limitation of phytsical activity. They are comfortable at rest. Less than ordinary physical activity causes fatigue, palpitation, dyspnea, or anginal pain.	22	14.7	37	14.6
CLASS	IV	Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of cardiac insufficiency or of the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.	122	81.3	214	83.6
MISSING DATA			6	4.0	3	1.2

[1] N = 150

[2] N = 256

Table 9-11
Current NYHA Functional Classification of
Living Heart Transplant Recipients

	CLASS	NUMBER OF PATIENTS	PERCENT OF PATIENTS
CLASS I	Patients with cardiac disease but without resulting limitations of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain.	132	88.0
CLASS II	Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain.	14	9.3
CLASS III	Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary physical activity causes fatigue, palpitation, dyspnea, or anginal pain.	0	0.0
CLASS IV	Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of cardiac insufficiency or of the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.	0	0.0
MISSING DATA		4	2.7

Table 9-12
Immunosuppressive Drugs Prescribed for Living Heart Transplant Recipients According to Three Specific Time Periods

	AFTER SURGERY		AT DISCHARGE		CURRENTLY	
DRUG	NUMBER	PERCENT	NUMBER	PERCENT	NUMBER	PERCENT
HORSE ATG	5	3.4	0	0.0	0	0.0
RABBIT ATG	69	46.6	0	0.0	0	0.0
OTHER ATG/ALG	14	9.3	5	3.4	0	0.0
METHYLPREDNISOLONE	125	85.0	0	0.0	0	0.0
AZATHIOPRINE	63	42.6	68	45.9	65	43.9
PREDNISONE	40	27.0	146	98.6	147	99.3
CYCLOPHOSPHAMIDE	3	2.0	4	2.7	6	4.1
CYCLOSPORINE	72	49.3	76	51.4	75	50.7
OTHER	1	0.7	0	0.0	0	0.0

Table 9-13
Immunosuppressive Drugs Prescribed for Deceased Heart Transplant Recipients According to Three Specific Time Periods

	AFTER SURGERY		AT DISCHARGE		AT DEATH	
DRUG	NUMBER	PERCENT	NUMBER	PERCENT	NUMBER	PERCENT
HORSE ATG	29	11.3	0	0.0	0	0.0
RABBIT ATG	118	46.3	0	0.0	0	0.0
OTHER ATG/ALG	58	22.7	6	2.3	10	3.9
METHYLPREDNISOLONE	224	87.5	0	0.0	16	6.3
AZATHIOPRINE	159	62.6	100	39.2	160	63.0
PREDNISONE	75	29.5	129	50.6	216	85.4
CYCLOPHOSPHAMIDE	13	5.1	7	2.7	10	3.9
CYCLOSPORINE	43	16.9	18	7.0	37	14.6
OTHER	2	0.8	2	0.8	24	9.5
EXPIRED PRIOR TO DISCHARGE			126	49.2		

deceased patients were at the time of their death (Oyer et al., 1983; Hardesty et al., 1983).

Data were also obtained on whether or not patients had received total lymphoid irradiation (TLI) or thoracic duct drainage (TDD) for purposes of immunosuppression (Bell et al., 1983; Modry et al., 1983; Niblack and Richie, 1983; Bach, 1981; Bach, 1975; Tilney and Murray, 1967). Among the living heart transplant recipients, none had received either TLI or TDD. Among the deceased patients, three had received TLI and one TDD.

7. INFECTION HISTORY

Infection is an admittedly serious problem for organ transplant recipients (Baumgartner, 1983). A variety of etiologic agents have been identified that can be broadly classified as bacterial, fungal, nocardial, viral, and protozoan. Table 9-14 shows the total number of infectious episodes among living and deceased heart transplant recipients according to etiologic agent and type of infection. The primary agents of infection have been herpes simplex and CMV. The average number of each infection per patient for both living and deceased heart transplant recipients are shown in Table 9-15. Overall, living heart transplant recipients experienced an average of 2.03 infectious episodes, deceased patients experienced 2.81 episodes, and all patients experienced 2.50 episodes.

8. REJECTION HISTORY

Rejection of the transplanted organ is also a common experience for transplant recipients. Table 9-16 shows a distribution of the number of rejection episodes experienced by both living and deceased patients. Of the living heart transplant recipients, 17 had

Table 9-14
Total Number of Infection Episodes Among Living and Deceased Heart Transplant Recipients According to Agent and Type of Infection

TYPE/AGENT	NUMBER OF EPISODES 1 LIVING RECIPIENTS	DECEASED RECIPIENTS	2 ALL RECIPIENTS
BACTERIAL INFECTIONS			
01 = Bacterial, unspecified	15	19	35
02 = Anaerobic, mixed	4	12	16
03 = Arizona	1	1	2
04 = Atypical A.F.B.	2	6	9
05 = Bordetella	1	0	1
06 = Citrobacter	0	1	1
07 = Clostridium	0	0	0
08 = Enterobacter	3	15	18
09 = Enterococcus	2	8	12
10 = Escherichia coli	12	23	45
11 = Hemophilus parainfluenzae	6	11	17
12 = Herellea	2	1	3
13 = Klebsiella	7	32	42
14 = Legionella pneumophilia	5	6	14
15 = Listeria	2	7	9
16 = Mima	0	1	2
17 = Neisseria	1	4	5
18 = Pneumococcus	3	6	9
19 = Proteus mirabilis	2	4	9
20 = Proteus morganii	2	2	4
21 = Pseudomonas sp.	11	27	39
22 = Salmonella	0	2	3
23 = Serratia	6	18	25
24 = Staphylococcus sp.	22	41	63
25 = Streptococcus	10	30	44
26 = Bacteriodes, Gen. Melan.	0	3	3
27 = Coryne Bacterium	0	2	2
28 = Mycoplasma	0	1	1
FUNGAL INFECTIONS			
30 = Fungal, unspecified	3	7	11
31 = Aspergillus	10	42	56
32 = Candida	13	33	49
33 = Coccidioides	1	1	2
34 = Cryptococcus	3	7	13
35 = Dreshsleria	0	1	1

Table 9-14 (Continued)
Total Number of Infection Episodes Among Living and Deceased Heart Transplant Recipients According to Agent and Type of Infection

TYPE/AGENT	NUMBER OF EPISODES		
	1 LIVING RECIPIENTS	DECEASED RECIPIENTS	2 ALL RECIPIENTS
36 = Mucor	0	0	0
37 = Rhizopus	0	1	1
38 = Yeast, unidentified	1	2	3
39 = Penicillium	0	1	1
VIRAL INFECTIONS			
40 = Viral, unidentified	2	7	9
41 = CMV	31	55	98
42 = Hepatitis	4	9	16
43 = Herpes simplex	56	50	123
44 = Herpes zoster	21	30	54
45 = Influenza A	0	1	1
46 = Varicella zoster	0	2	2
47 = EBV (Epstein Barr virus)	1	1	2
PROTOZOAN INFECTIONS			
50 = Protozoan, unspecified	0	0	0
51 = Pneumocystis	5	27	32
52 = Histoplasma	0	1	1
53 = Toxoplasma	1	5	6
54 = Trichomonas	1	3	4
NOCARDIAL INFECTIONS			
60 = Nocardial	12	22	38
88 = Only site of infection listed, agent unspecified	24	129	153
TOTAL	308	720	1109

[1]Includes only those patients who completed a patient survey.

[2]Also includes living patients who did not complete a patient survey.

Table 9-15
Average Number of Infection Episodes Per Patient Among
Living, Deceased, and All Heart Transplant Recipients
According to Agent and Type of Infection

	AVERAGE NUMBER OF EPISODES					
	LIVING[1] RECIPIENTS		DECEASED RECIPIENTS		ALL[2] RECIPIENTS	
TYPE/AGENT	MEAN	S.D.	MEAN	S.D.	MEAN	S.D.
BACTERIAL INFECTIONS						
01 = Bacterial, unspecified	.099	.427	.074	.304	.079	.343
02 = Anaerobic, mixed	.026	.161	.047	.230	.036	.198
03 = Arizona	.007	.081	.004	.063	.005	.067
04 = Atypical A.F.B.	.013	.114	.023	.176	.020	.156
05 = Bordetella	.007	.081	.000	.000	.002	.047
06 = Citrobacter	.000	.000	.004	.068	.002	.047
07 = Clostridium	.000	.000	.000	.000	.000	.000
08 = Enterobacter	.020	.140	.059	.281	.041	.229
09 = Enterococcus	.013	.114	.031	.174	.027	.162
10 = Escherichia coli	.079	.391	.129	.437	.101	.404
11 = Hemophilus parainfluenzae	.039	.195	.043	.357	.038	.294
12 = Herellea	.013	.114	.004	.063	.007	.082
13 = Klebsiella	.046	.210	.125	.406	.095	.349
14 = Legionella pneumophilia	.033	.179	.023	.176	.032	.187
15 = Listeria	.013	.114	.027	.163	.020	.141
16 = Mima	.000	.000	.004	.063	.005	.067
17 = Neisseria	.007	.081	.016	.124	.011	.106
18 = Pneumococcus	.020	.140	.023	.152	.020	.141
19 = Proteus mirabilis	.020	.181	.016	.153	.020	.170
20 = Proteus morganii	.013	.114	.008	.088	.009	.095
21 = Pseudomonas sp.	.072	.347	.105	.443	.088	.396
22 = Salmonella	.000	.000	.008	.088	.007	.082
23 = Serratia	.039	.195	.070	.311	.056	.267
24 = Staphylococcus sp.	.145	.405	.160	.562	.142	.489
25 = Streptococcus	.066	.249	.117	.418	.099	.367
26 = Bacteriodes (Gen)	.000	.000	.012	.108	.007	.082
27 = Corvne Bacterium	.000	.000	.008	.088	.005	.067
28 = Mycoplasma	.000	.000	.004	.063	.002	.047
FUNGAL INFECTIONS						
30 = Fungal, unspecified	.020	.140	.027	.163	.025	.156
31 = Aspergillus	.066	.249	.164	.439	.126	.377
32 = Candida	.086	.303	.129	.437	.110	.385
33 = Coccidioides	.007	.081	.004	.063	.005	.067
34 = Cryptococcus	.020	.140	.027	.186	.029	.194
35 = Dreshsleria	.000	.000	.004	.063	.002	.047

Table 9-15 (Continued)
Average Number of Infection Episodes Per Patient Among Living, Deceased, and All Heart Transplant Recipients According to Agent and Type of Infection

	AVERAGE NUMBER OF EPISODES					
	LIVING[1] RECIPIENTS		DECEASED RECIPIENTS		ALL[2] RECIPIENTS	
TYPE/AGENT	MEAN	S.D.	MEAN	S.D.	MEAN	S.D.
36 = Mucor	.000	.000	.000	.000	.000	.000
37 = Rhizopus	.000	.000	.004	.063	.002	.047
38 = Yeast, unidentified	.007	.081	.008	.088	.007	.082
39 = Penicillum	.000	.000	.004	.063	.002	.047
VIRAL INFECTIONS						
40 = Viral, unidentified	.013	.114	.027	.186	.020	.156
41 = CMV	.204	.493	.215	.536	.221	.517
42 = Hepatitis	.026	.198	.035	.185	.036	.198
43 = Herpes simplex	.368	.658	.195	.435	.277	.564
44 = Herpes zoster	.138	.383	.117	.346	.122	.354
45 = Influenza A	.000	.000	.004	.063	.002	.047
46 = Varicella zoster	.000	.000	.008	.088	.005	.067
47 = EBV (Epstein Barr virus)	.007	.081	.004	.063	.005	.067
PROTOZOAN INFECTIONS						
50 = Protozoan, unspecified	.000	.000	.000	.000	.000	.000
51 = Pneumocystis	.033	.213	.105	.355	.072	.299
52 = Histoplasma	.000	.000	.004	.063	.002	.047
53 = Toxoplasma	.007	.081	.020	.139	.014	.116
54 = Trichomonas	.007	.081	.012	.108	.009	.095
NOCARDIAL INFECTIONS						
60 = Nocardial	.079	.336	.086	.366	.086	.352
88 = Only site of infection listed, agent unspecified	.158	.621	.465	.902	.345	.809

[1]Includes only those patients who completed a patient survey.

[2]Also includes living patients who did not complete a patient survey.

Table 9-16
Number of Rejection Episodes Experienced By
Heart Transplant Recipients

	LIVING RECIPIENTS		DECEASED RECIPIENTS	
NUMBER OF REJECTION EPISODES	NUMBER	PERCENT	NUMBER	PERCENT
0	17	11.2	54	21.1
1	34	22.4	55	21.5
2	33	21.7	55	21.2
3	30	19.7	39	11.3
4	14	9.2	25	9.8
5	6	3.9	19	7.4
6	3	2.0	6	2.3
7	3	2.0	7	2.7
8	3	2.0	2	0.8
9	2	1.3	3	1.2
MISSING DATA	7	4.6	1	0.4

experienced no rejection episodes. The majority of patients have experienced between 1 and 3 rejection episodes. In this study, living heart transplant recipients experienced an average of 2.46 (S.D. = 1.94) rejection episodes, while deceased patients experienced an average of 2.26 (S.D. = 2.03) episodes.

9. HISTOCOMPATIBILITY

The desperate clinical status of patients awaiting cardiac transplantation precludes an excessive waiting period for a histo-compatibile donor. In all cases, ABO blood group compatibility and a negative cross-match between recipient serum and donor lymphocytes is sought prior to transplantation. As noted by Oyer et al. (1981), other matching systems, which require several days of cell culture, have not been useful for the additional reason that cadaver donors cannot be maintained for the requisite time to complete the required assay. Retrospective analysis of histocompatibility data from Stanford has failed to show a significant correlation between the number of HLA antigens mismatched, and postoperative survival or rejection history. Despite this, there is some evidence that an A2 antigen mismatch may be associated with a higher rate of development of allograft coronary atherosclerosis (Oyer et al., 1981).

Results pertinent to histocompatibility for both living and deceased heart transplant recipients in this study are presented in Tables 9-17, 9-18, and 9-19. In Table 9-17, the results of the lymphocyte crossmatch test are shown. Clearly, for the majority of patients, the results of this test are unknown (64.6 percent for living patients and 68.8 percent for deceased patients). As expected,

Table 9-17
Results of Lymphocyte Crossmatch Test

	LIVING PATIENTS		DECEASED PATIENTS	
LYMPHOCYTE CROSSMATCH	NUMBER	PERCENT	NUMBER	PERCENT
NEGATIVE	50	33.3	73	28.5
POSITIVE	3	2.0	7	2.7
UNKNOWN	97	64.6	176	68.8

Table 9-18
Number of HLA Antigen Matches Across All Loci

NUMBER OF HLA MATCHES (ALL LOCI)	LIVING PATIENTS		DECEASED PATIENTS	
	NUMBER	PERCENT	NUMBER	PERCENT
0	45	30.0	85	33.2
1	48	32.0	101	39.5
2	22	14.7	27	10.5
3	13	8.7	3	1.2
4	0	0.0	1	0.4
5	3	2.0	0	0.0
6	2	1.3	0	0.0
UNKNOWN	17	11.3	39	15.3

Table 9-19
Number of HLA Matches Across the A and B Loci Only

NUMBER OF HLA MATCHES (A and B LOCI ONLY)	LIVING PATIENTS		DECEASED PATIENTS	
	NUMBER	PERCENT	NUMBER	PERCENT
0	49	32.7	90	35.2
1	49	32.7	103	40.2
2	23	15.3	21	8.2
3	11	7.3	3	1.2
4	0	0.0	0	0.0
5	0	0.0	0	0.0
6	1	0.7	0	0.0
UNKNOWN	17	11.3	39	15.2

the percent of patients where the crossmatch test was positive is very small (about 2.0-2.7 percent).

In Table 9-18, the number of HLA antigens matched across all loci is presented. Rather than examine mismatches only, where the denominator is determined by the number of tests performed, we looked at the number of antigen matches regardless of the number of tests performed. Clearly there is considerable similarity between the living and deceased patients with regard to HLA compatibility with the exception of those living recipients who had a three antigen match.

In Table 9-18, we focus on the HLA-A and B antigens only. Once again there is substantial similarity between both living and deceased patients, although living recipients are more likely to have a three antigen match. Only three deceased patients had a three antigen match compared with 11 living patients.

These analyses of histocompatibility are very simple and gross. A much more detailed analysis is required to determine if HLA compatibility appears to have a positive effect on patient outcomes. For example, patients may be examined according to various transplant periods (e.g., pre versus post-cyclosporine era) to see if there are noticeable differences. Also, one could examine only patients on conventional therapy who have been transplanted over a predefined period of time. In short, the results presented here are inconclusive. Further analyses are required to sort out the effect of various histocompatibility factors.

10. COMORBIDITY

Comorbidity among organ transplant recipients is an important consideration both before and following transplant surgery (Penn,

1979; 1982; 1983; Kay, 1983; Lanza et al., 1983; Kenzora and Tilney, 1982; Burns, 1982; Tilney and Lazarus, 1982; Salaman, 1983; Murray, 1973; Crosnier, 1981). In general, the presence of severe comorbidity is considered a contraindication to transplantation. It is also apparent, however, that severe comorbidity may develop as a consequence of immunosuppressive therapy (see Chapter 4). Most significant among these conditions are cancer, bone disease, peptic ulcer disease, diabetes, and vision disorders.

The medical records of all heart transplant recipients were abstracted to determine the prevalence of comorbidity. A determination was made as to the presence of selected conditions before transplantation, now or at the time of death (in the case of deceased transplant recipients), and both before and after transplantation. Once again, two tables have been prepared to present the results: Table 9-20 for living patients and Table 9-21 for deceased patients.

As shown in Table 9-20, the five most prevalent complications among living heart transplant recipients posttransplant, excluding patients who had the conditions both pre- and posttransplant, are (1) osteoporosis (18.2%), (2) diabetes (14.9%), (3) vision disorders (14.3%), (4) back or spine disorders (8.8%), and (5) cancer (6.1%). All of these are associated with immunosuppressive therapy and, not surprisingly, most patients acquired these problems subsequent to their transplant.

Posttransplant complications were also prevalent among deceased heart transplant recipients. As shown in Table 9-21, the five leading complications among this group, once again excluding patients who had the conditions both pre- and posttransplant, are:

Table 9-20
Comorbidity Among Living Heart Transplant Recipients[1]

	NEVER	PRE-TRANSPLANT	POST-TRANSPLANT	BOTH
Cancer	93.2	0.7	6.1	0.0
Chronic Lung Disorder	93.9	2.7	5.4	2.0
Stomach Ulcer	93.9	2.1	4.8	0.7
Chronic Kidney Disorder	95.9	1.4	3.4	0.7
Diabetes	83.8	1.4	16.3	1.4
Epileptic Seizures	97.3	0.7	2.0	0.0
Osteoporosis	80.4	1.4	18.9	0.7
Back or Spine Disorder	91.2	0.0	8.8	0.0
Vision (sight) Disorder	75.5	10.2	23.8	9.5
Nervous or Emotional Problems	93.2	3.4	6.8	3.4
Mental Disorder	98.6	0.0	1.4	0.0
Alcohol or Drug Problems	93.9	5.5	1.4	0.7
Sleep Disorder	97.9	0.0	2.1	0.0

N = 150

[1]Percentages do not total 100.0 because the same patient may appear in more than one category.

Table 9-21
Comorbidity Among Deceased Heart Transplant Recipients[1]

	NEVER	PRE-TRANSPLANT	POST-TRANSPLANT	BOTH
Cancer	89.9	1.2	9.1	0.0
Chronic Lung Disorder	94.9	1.6	4.8	1.2
Stomach Ulcer	90.6	2.0	8.7	1.2
Chronic Kidney Disorder	93.3	1.2	6.3	0.8
Diabetes	80.7	4.4	17.8	2.8
Epileptic Seizures	89.3	1.2	9.9	0.4
Osteoporosis	89.7	1.2	9.9	0.8
Back or Spine Disorder	92.9	0.8	6.7	0.4
Vision (sight) Disorder	87.0	2.8	12.3	2.0
Nervous or Emotional Problems	90.5	3.2	8.7	2.4
Mental Disorder	93.7	0.4	5.9	0.0
Alcohol or Drug Problems	93.7	5.2	2.0	0.8
Sleep Disorder	96.4	2.0	1.6	0.0

N = 256

[1]Percentages do not total 100.0 because the same patients may appear in more than one category.

(1) diabetes (15.0%), (2) vision disorders (10.3%), (3) epileptic seizures (9.5%), (4) cancer (9.1%), and (5) osteoporosis (9.1%). As shown, the analysis reveals that most patients did not have these conditions prior to transplantation.

In reviewing Tables 9-20 and 9-21 perhaps what is most striking is the relatively low prevalence of comorbidity among heart transplant recipients. In most instances, comorbidity is characteristic of a relatively small number of patients. It is true, however, that the development of posttransplant complications remains one of the foremost concerns of transplant physicians.

C. SOCIAL AND FAMILY CONSIDERATIONS

Above, some discussion was devoted to the marital status and marital relationships of living heart transplant recipients. This discussion will now be expanded to include other social relationships of which the patient is a part. The family, of course, is among the most important of social relationships (Parad and Caplan, 1960; Hill and Hansen, 1964; Hill, 1949; Murphy, 1982; Klein et al., 1967; Salk et al., 1972; Donald et al., 1978).

When asked about their immediate family, 50.7 percent of the patients described their family as "very close," 34.9 percent as "pretty close," 12.5 percent as "somewhat close," and 2.0 percent as "not at all close." Over 95 percent of the patients felt that people in their family got along very well or pretty well at home. Of the 121 patients who had children, 30.3 percent said they were very or somewhat satisfied with their relations with their children. The majority of all families appear to be quite close, as nearly 40

percent of the patients said they "very often" do things together. Only 2.6 percent of patients said their families "never" do anything together.

In reflecting on their heart transplant experience, 66.4 percent of the patients indicated that they and their family were "extremely worried" when they first found out that the patient required a transplant. Only 7.9 percent of the patients indicated that they were "not at all worried," often because they were "close to death" and the operation gave them a chance to extend their life. Most (57.9 percent) of the patients characterized their family situation while they were sick as "very tense and nervous." Only two patients described their family situation at that time as "not at all tense or nervous." The majority of patients (53.9 percent) feel that their family has been "very upset" with their disease, and 28.3 percent feel their family is "somewhat upset."

Clearly heart disease and heart transplantation have been a substantial imposition on the family situation. Just over 46 percent of the patients believe that their heart transplant has taken "a lot of their family's time and energy;" 28.3 percent "some of their family's time and energy," and 25.0 percent "a little of their family's time and energy." Family routine appears to have been interfered with as 23.0 percent of the patients describe this interference as occurring "often." Only 11.2 percent of the patients said their heart transplant has not interfered with family routine at home. Just over 15 percent of the patients believe that their heart transplant has led to family resentment.

When asked how much various people in their family had to give up because of their heart transplant, 31.6 percent of the patients felt they had to give up "very much." Of the married patients, 40.2 percent felt their spouse had to give up "very much," and 16.9 percent felt their children had to give up "very much."

The majority of patients (55.9) felt their family understands "very well" how they feel about their heart transplant, 48.0 percent "somewhat well" and, 12.5 percent "not very well." Only 18.4 percent of the patients felt their families often "watch them too carefully" subsequent to their transplant. About 55 percent of the patients felt their families watched them "sometimes" too carefully. The remaining patients felt that this never occurred.

Most heart transplant recipients indicated that their families talk about their heart transplant. Twenty-eight percent said this occurred "frequently," 66 percent "sometimes," and the remainder said "never." Thus, it is not surprising that 50 percent of the patients said their heart transplant causes their family "some" worry, 4 percent a "great amount of worry," 38 percent a "small amount of worry," and the remainder "no worry."

In terms of problems heart transplant recipient families have faced, 38.8 percent said that their heart transplant was "a very great problem," 34.2 percent said "somewhat of a problem," and the remainder said either "a small problem" or "no problem at all." Interestingly, however, 69.7 percent of the patients felt their heart transplant had brought their family closer together.

Most heart transplant recipients are quite active socially. When asked: "Over a year's time about how often do you get together

with friends or relatives, like going out together or visiting in each other's homes," 0.7 percent of the recipients said every day; 21.7 percent, several days a week; 28.9 percent, about once a week; 22.4 percent, 2 or 3 times a month; 9.2 percent, about once a month; 8.6 percent, 5 to 10 times a year; and 7.9 percent, less than 5 times a year. Table 9-22 summarizes how often patients participated in a variety of activities in a one-month period including having friends over, visiting friends in their homes, calling or receiving a telephone call from friends or relatives, and writing a letter to a friend or relative. With the exception of writing letters, heart transplant recipients are quite active socially.

Over 54 percent of the patients belong to one or more voluntary groups or organizations such as church groups, clubs or lodges, parent groups, and so forth. Of this 54 percent, nearly 20 percent of the patients were members of one group; 14 percent, two groups; 13 percent, three groups; 5 percent, four groups; and the rest, five or more groups. In characterizing their level of activity in the affairs of these groups, 26.8 percent said they were "very active," 46.3 percent, "fairly active," and 26.9 percent, "not active."

D. PERSONAL ADJUSTMENT

The majority of the living heart transplant recipients perceive themselves as having adjusted well to their heart transplant experience. For example, when asked a very general question about how well they think they have adjusted, 71.1 percent of the patients said "very well" and 27.0 percent said "fairly well." One patient said

Table 9-22
Social Activities in Which Heart Transplant Recipients
Engaged Over A One-Month Period

FREQUENCY	HAD FRIENDS OVER	VISITED FRIENDS	TELEPHONE CALL	WRITE A LETTER
Every Day	.7	1.3	22.4	.7
Several times a week	20.4	13.2	36.2	3.9
About once a week	16.4	21.1	22.4	7.9
2 or 3 times in past month	32.9	30.3	15.1	13.2
Once in past month	11.8	13.8	3.3	12.5
Not at all in past month	17.1	20.4	0.0	61.8
Didn't Answer	.7	0.0	0.0	0.0

"not too well," one patient said "fairly poorly," and no patients said "very poorly," although one patient refused to answer the question.

In describing the period since their heart transplant, 54.6 percent of the patients felt it was better than expected, 25.7 percent felt it was about as expected, and 17.8 percent said it was worse than expected. Three patients refused to answer this question or provided responses that could not be coded.

All patients were asked to think back over the time since they received their transplant and then indicate how often they felt that it was a mistake to have had a heart transplant. The responses were as follows: 74.3 percent, "never;" 13.8 percent, "almost never;" 9.2 percent, "sometimes;" 2.0 percent, "very often;" and 0.7 percent, "always."

Nearly 80 percent of the patients felt that they were well informed by doctors and transplant center staff before the operation about the transplant procedure and recovery.

Although most patients clearly have a very strong will to live, they have also come to terms with their own mortality. For example, when asked how strongly they agree with the statment "I have a strong will to live," 120 patients said they strongly agree, 27 agreed, 3 patients were not sure, 1 patient disagreed, and 1 patient refused to respond. Yet, when asked how strongly they agreed with the statement "It is difficult for me to accept the fact that I may die from this illness," 18 patients said they strongly agreed, 25 agreed, 12 were not sure, 53 disagreed, and 43 strongly disagreed with the statement. Again, one patient refused to respond. Moreover, when asked how strongly they agreed with the statement "A person should have the

right to decide to die," 62 patients strongly agreed, 44 patients agreed, 27 patients were unsure, 12 patients disagreed, 6 patients strongly disagreed, and one patient refused to respond to the statement. Clearly, death does not appear to be an insurmountable problem for these patients.

Although the quality of life of heart transplant recipients is the subject of extensive analyses in Part 7 of this report, perhaps it is fitting at this point to comment on the overall level of happiness among heart transplant recipients. All patients were asked the following question: "If you were to compare yourself now to the time before you had your heart transplant, do you think you are generally, (1) happier than you were before you had a transplant, (2) less happy, or (3) about as happy as you were before?" In responding, 57.9 percent of the patients said they were happier, 18.4 percent said they were less happy, 20.4 percent said they were about as happy, and 3.3 percent of the patients said they could not remember how they used to feel.

Patients were also asked a very general question about how happy they are these days. Exactly 50.0 percent of the patients said they were "very happy," 37.5 percent said "pretty happy," and 11.8 percent said "not too happy." One patient refused to respond to the question. It turns out, that when compared with the general population of the United States, heart transplant recipients actually express a higher level of happiness. Table 9-23 shows the responses of the general population to our happiness question for several years (see Campbell et al., 1976:26).

Table 9-23
Levels of Happiness Expressed By the General Population
and Heart Transplant Recipients
(Expressed As A Percent)

YEAR/GROUP	VERY HAPPY	PRETTY HAPPY	NOT TOO HAPPY
1957 GENERAL POPULATION[1]	35	54	11
1963 GENERAL POPULATION[1]	32	52	16
1965 GENERAL POPULATION[1]	30	53	17
1971 GENERAL POPULATION[1]	29	61	10
1972 GENERAL POPULATION[1]	26	65	9
1972 GENERAL POPULATION[1]	22	68	10
1983 HEART TRANSPLANT RECIPIENTS	50.0	37.5	11.8

[1]SOURCE: Campbell et al., 1976:26.

E. PERCEIVED HEALTH STATUS

Perceived health status is considered to be an important aspect of one's recovery from severe illness and their ability to cope with chronic disease. Although a heart transplant recipient is not truly cured of their heart condition, they, nonetheless, are generally in better health than prior to their transplant. The rather complicated posttransplant course of all patients, however, is a constant reminder that their health has been compromised. For example, all patients will continue to take immunosuppressive drugs that have a variety of untoward side-effects. Thus, in the end, transplant patients exchange poor health for a life where drugs necessary to combat rejection may ultimately threaten their health and well-being.

Humans are remarkably resilient, and the responses to the questions concerning perceived health status among heart transplant recipients are not surprising. As in other respects, heart transplant recipients have exhibited remarkable adaptation.

Patients were first asked how their health compared with other people their age. In responding to this question, the patients who responded appeared realistic. Fifteen patients (9.9 percent) said their health was better, 40.8 percent said "about the same," and 48.0 percent said "poorer." Two patients did not respond to the question. Patients were then asked how satisfied they were with their "health at this time." The majority of patients indicated some level of positive satisfaction. Their responses were as follows: 19.1 percent, completely satisfied; 21.1 percent, very satisfied; 36.2 percent, satisfied; 13.2 percent, neutral; 6.6 percent, dissatisfied; 2.0 percent, very dissatisfied; and 2.0 percent, completely dissatisfied.

Thus, only 10.6 percent of the patients indicated some level of negative satisfaction with their health.

All patients were later asked to rate their health status at various key points in time--now, five years ago, and the year before they had their heart transplant. When asked, "How would you rate your overall health at the present time?" 14.6 percent of the patients said excellent; 50.7 percent, "good;" 27.5 percent, "fair;" and 7.2 percent, "poor." When asked, "Is your health now better, about the same, or worse than it was five years ago?", 32.9 percent of the patients said "better;" 29.6 percent, "about the same;" and 36.8 percent, "worse." One patient did not respond to this question. Finally, when asked, "Is your health now better, about the same, or worse than it was the year before you had your heart transplant?" the patients responded as follows: 70.4 percent, "better;" 11.8 percent, "about the same;" and 17.1 percent, "worse." Again, one patient did not respond to this question.

F. PHYSICAL FUNCTIONING

Although considered at greater length in Chapters 23 through 26 of this report, physical functioning is also an important consideration in the ability of a person to respond to severe illness. All patients in the study were asked an extensive battery of questions pertaining to their level of functioning. The intent here is to provide an overview of the levels of activity in which patients are able to engage and to indicate how their overall functional status has changed between two time periods--one year prior to transplant and currently.

In the quality of life chapters of this report, additional data will be presented using different indicators of functional ability.

The patients were asked to provide some indication of the number of hours per week in the past month that they engaged in "light," "medium," and "strenuous" activities (Stewart et al., 1978; 1981). "Light" activities included the following: standing or walking slowly, bowling, fishing quietly, playing a musical instrument, and mowing the lawn with a power mower. "Medium" activities included the following: bicycling, playing golf, dancing, canoeing (not white water), digging or gardening, doing carpentry, and swimming slowly. Finally, "strenuous" activities included the following: carrying heavy weights (80 pounds or more), shoveling heavy loads, jogging or running fast, skiing, playing full court basketball, playing handball or squash, and playing touch football. Table 9-24 summarizes these activities for all heart transplant recipients. Not surprisingly, the majority of heart transplant recipients engage in light activities, with slightly fewer involved in medium activities, and just over 25 percent undertaking strenuous activities.

The patients were also asked about a variety of activities in which they engaged the year before their heart transplant and at the present time. A complete list of activities, as well as an indication of whether patients engaged in them is shown in Table 9-25. Clearly, in the aggregate, all patients showed a marked improvement between the time before their heart transplant and currently. This does not, of course, mean that each patient improved. If individual patient comparisons were made, there may be evidence of decline. In the aggregate, however, such decline is not apparent.

Table 9-24
Summary of Type and Level (Hours Per Week) of Physical Activities In Which Heart Transplant Recipients Engaged In The Past Month
(Expressed As A Percent)

HOURS PER WEEK	LIGHT ACTIVITIES	MEDIUM ACTIVITIES	STRENUOUS ACTIVITIES
NO HOURS PER WEEK	.7	19.1	71.7
1 HOUR	17.1	5.3	5.3
2 to 5 HOURS	23.7	27.6	12.5
6 to 10 HOURS	25.0	25.0	7.2
11 to 15 HOURS	7.9	10.5	0.0
16 HOURS OR MORE	25.0	12.5	3.3
DON'T KNOW	.7	0.0	0.0

Table 9-25
Limitations Heart Transplant Patients Experienced One-Year Before
Their Heart Transplant And Those Experienced Currently
(Expressed As A Percent)

	TIME PERIOD	
BECAUSE OF HEALTH DID/DOES PATIENT	BEFORE	NOW
Need assistance traveling around community	32.9	8.6
Stay indoors most or all of the day because of health	41.4	6.6
Stay in bed most or all of the day because of health	41.4	6.6
Limited in vigorous activities	75.7	70.4
Trouble walking several blocks or climbing stairs because of health	73.0	34.2
Trouble bending, stooping, or lifting because of health	63.8	43.4
Trouble walking one block or climbing one flight of stairs because of health	62.5	16.4
Help in walking such as another person, cane, crutches, etc.	17.8	7.2
Unable to do certain amounts of work, housework, or schoolwork	71.1	52.6
Unable to work at job or do work around house	63.8	47.4
Need help eating, dressing, bathing, or using toilet	13.8	1.3
Limited in any way from doing anything he wants to	73.0	66.4

Two questions were also included in the questionnaire that provided a gross characterization of activity level. The first question and the percentage distribution of the responses was as follows: "Which statement describes you best?"

Not very active, sitting and walking mostly	39.9%
A weekend or vacation exerciser	5.3%
Physically active at least 1-2 times during the week	16.4%
Physically active 3 or more times during the week	44.7%

One patient refused to answer this question. As shown, fully one-third of the patients are not very active, but nearly 45 percent are quite active.

The second question intended to summarize overall activity level pertained only to the past month. The patients were asked: "Which of the following statements best describes your life during the past month?" Patient activity level according to the major response categories is revealed in Table 9-26. Clearly, over half of the patients have made what could be considered a reasonable recovery, although 14.5 percent were up most of the day but were quite restricted in activity. Only one patient (.7 percent) was confined to a wheelchair when out of bed.

G. EMPLOYMENT

Numerous questions were asked of patients concerning employment. Since the subject of Chapter 23 is the work status of heart transplant recipients, data will be summarized here pertaining only to current

Table 9-26
Overall Assessment of Physical Activity By Heart Transplant Recipients For The Past Month

ACTIVITY LEVEL	PERCENT AGREEING
Well and doing most things I did before my illness	51.3
Well but not performing many customary activities	32.9
Up most of the day but quite restricted activity	14.5
Confined to a wheelchair when out of bed	0.7
Confined to bed but feeling well	0.0
Confined to bed and not feeling well	0.0
REFUSED TO RESPOND	0.7

employment status. Chapter 23 will further elaborate on pretransplant employment activity of patients, their ability to participate in the labor force, and problems patients have encountered in maintaining a job.

As shown in Table 9-27, 48 patients (31.6 percent) were either employed full-time or part-time. The majority of the patients (50.7 percent) were unable to work because of their health. Only 5 patients were homemakers, 3 were students, and 12 had retired. Six patients indicated that they were unemployed but looking for work.

H. INCOME AND FINANCES

The discussion that follows concerns the overall income of patients as well as their financial status. Insofar as appropriate, some data are also reported on the manner in which the recipients of heart transplants financed their transplant procedure. This, of course, is not unrelated to the income status of patients since most patients incur a considerable financial burden before, during, and following their heart transplant.

1. INCOME AND NET WORTH

Patients were asked to estimate their total family income from all sources in 1982. The following sources of income were listed on the questionnaire: (1) your wages and/or salary, (2) spouses wages and/or salary, (3) income from pensions, Social Security disability benefits, and (4) income from all other sources. Fifteen patients (9.7 percent) refused to disclose their income, and three patients (2.0 percent) indicated that they did not know. Table 9-28 shows the income distribution of those patients who were willing to provide the requested information. Clearly, the household incomes of heart

Table 9-27
Current Employment Status of Living Heart Transplant Recipients

EMPLOYMENT STATUS	NUMBER OF PATIENTS	PERCENT OF PATIENTS
EMPLOYED FULL-TIME	38	25.0
EMPLOYED PART-TIME	10	6.6
EMPLOYED BUT TEMPORARILY LAID OFF	0	0.0
UNEMPLOYED, LOOKING FOR WORK	6	3.9
UNEMPLOYED, NOT LOOKING FOR WORK	0	0.0
UNABLE TO WORK BECAUSE OF HEALTH (DISABLED)	77	50.7
HOMEMAKER	5	3.3
STUDENT (FULL-TIME)	3	2.0
RETIRED	12	7.9
OTHER	1	0.7

Table 9-28
Income Distribution of Living Heart Transplant Recipients in 1982

INCOME RANGE	NUMBER OF PATIENTS*	PERCENT OF PATIENTS
$0 - $2,499	5	3.7
$2,500 - $4,999	4	3.0
$5,000 - $7,499	8	6.0
$7,500 - $9,999	7	5.2
$10,000 - $14,999	20	14.9
$15,000 - $19,999	25	18.7
$20,000 - $24,999	9	6.7
$25,000 - $29,999	10	7.5
$30,000 - $39,999	16	11.9
$40,000 - $74,999	22	16.4
$75,000 +	8	6.0
	134	100.0

*18 patients refused to provide or did not know their income.

transplant recipients were well above those of the general U.S. population. This is particularly true in the $75,000-plus income range.

The net worth of patients was ascertained by asking them to compare their total assets with their total debts, assuming they were to sell their cars, house, property and so forth and then pay off their debts. Taking the amount left, they were to add money they had in checking accounts, credit unions, stocks, and bonds. This total would then be an approximation of their net worth. Once again, 15 patients refused to do this and 3 stated that they did not know. Of the 134 patients who provided the information, the distribution of patients according to general net worth categories was as follows: 43.3 percent, less than $10,000; 14.9 percent, $10,000-$24,999; 11.9 percent, $25,000-$49,999; 10.4 percent, $50,000-$99,999; 9.7 percent, $100,000-$199,999; and 9.7 percent, $200,000 or more.

As shown in Table 9-29, many patients are currently receiving some form of income support through a variety of programs, the primary source being Social Security Retirement or Disability benefits. Ninety-five patients (62.5 percent) receive some benefits from Social Security at the present time. The next most frequently used source of benefits is union or employment disability benefits.

Overall, it is quite interesting to note that the patients in the study, when compared with people in the general population, seemed rather satisfied with their standard of living as well as with their savings and investments. The responses to two questions dealing with these areas are summarized in Table 9-30. As shown here, patients are clearly less satisfied with their savings and investments than they

Table 9-29
Sources of Income Support For Living Heart Transplant Recipients

SOURCE OF INCOME SUPPORT	NUMBER AND PERCENT RECEIVING ASSISTANCE	
	NUMBER	PERCENT*
Social Security Retirement or Disability Benefits	95	62.5
Supplemental Security Income	5	3.3
Railroad Retirement Benefits	0	0.0
Veterans Administration Benefits	13	8.6
Unemployment Compensation	0	0.0
Workmen's Compensation	1	0.7
Aid to Families With Dependent Children	3	2.0
Civil Service Benefits	1	0.7
Union or Employer Disability Benefits	27	17.8
Union or Employer Retirement or Pension Benefits	7	4.6
Other Benefits	14	9.2

*Does not total 100 percent because a person could receive benefits from more than one source.

Table 9-30
Satisfaction With Standard of Living and Savings and Investments
As Expressed By Living Heart Transplant Recipients
and the General Population
(Expressed As A Percent)

	STANDARD OF LIVING		SAVINGS AND INVESTMENTS	
RESPONSE	HEART TRANSPLANT RECIPIENTS	GENERAL[1] POPULATION	HEART TRANSPLANT RECIPIENTS	GENERAL[1] POPULATION
COMPLETELY SATISFIED	14.5	28.0	5.3	19.0
VERY SATISFIED	16.4	25.0	12.5	16.0
SATISFIED	34.2	19.0	21.7	14.0
NEUTRAL	14.5	14.0	19.1	15.0
DISSATISFIED	18.4	7.0	24.3	11.0
VERY DISSATISFIED	1.3	4.0	7.9	10.0
COMPLETELY DISSATISFIED	0.0	3.0	7.2	15.0
NO ANSWER	0.7	0.0	2.1	0.0

[1]SOURCE: Campbell et al., 1976.

are with their standard of living. Nearly two-thirds of the patients expressed some level of satisfaction with their standard of living, while only 39.5 percent did so with regards to their savings and investments.

2. FINANCES

As noted above, paying for a heart transplant is, for most patients, a substantial undertaking. Although 82 percent of all living heart transplant recipients have at some time received assistance from a private insurer to cover their expenses, coverage is by no means universal (see Chapter 40). Table 9-30 provides a summary of all sources of payment for transplant-related expenses incurred by living heart transplant patients according to three specific points in the heart transplant trajectory. These findings, along with others, are elaborated upon in Chapter 40. It is clear, however, from Table 9-31 that many patients have incurred out-of-pocket expenses associated with their transplant.

All patients were asked about finances as a source of worry at the time of their transplant and at the present time. As shown in Table 9-32, the level of worry among transplant recipients has shifted only slightly from the time of their transplant until now. At the time of transplant, 64.5 percent of the patients said they were extremely or moderately worried, while 60.5 percent of the patients now express this same level of worry.

Patients were specifically asked whether the information they received on transplant costs prior to their transplant was accurate. In responding to this question, 4 patients refused to respond or provided responses that could not be coded. Of the 148 patients who

Table 9-31
Sources of Payment For Medical Expenses Incurred By Living Heart Transplant Recipients According to Transplant Period (Expressed As A Percent)

	TRANSPLANT PERIOD*		
SOURCE OF PAYMENT	PRETRANSPLANT	TRANSPLANT	POSTTRANSPLANT
Out-of-Pocket	67.8	40.8	68.4
Private Insurance	71.7	66.4	73.7
Medicare	15.1	14.5	32.3
Medicaid	5.9	5.3	9.2
Transplant Center	19.7	53.3	40.8
Direct Donations	27.0	16.4	12.5
CHAMPUS Program	.7	.7	.7
Veteran's Administration	7.2	3.9	5.9
Other	7.9	3.3	4.6

*Totals exceed 100.0 percent because a person could have multiple sources of payment.

Table 9-32
Finances As A Source Of Worry For Living Heart Transplant Recipients
(Expressed As A Percent)

	TIME PERIOD	
LEVEL OF WORRY	AT TIME OF TRANSPLANT	NOW
EXTREMELY WORRIED	38.8	21.7
MODERATELY WORRIED	25.7	38.8
A LITTLE WORRIED	19.1	21.1
NOT AT ALL WORRIED	16.4	18.4

did respond, 52.7 percent said they were adequately informed, 15.5 percent said they were not adequately informed, and 31.8 percent said that they were provided with no information on costs. Overall, however, nearly 80 percent of the patients felt they were well-informed by doctors and transplant center staff before the operation about the transplant procedure and recovery.

I. CONCLUSION

This chapter has provided a detailed descriptive overview of living heart transplant recipients. Where appropriate, data have also been presented on deceased heart transplant recipients. All aspects of the heart transplant recipient's experience have been discussed, social as well as medical. We began with a detailed sociodemographic description of the patients which demonstrated that the majority of heart transplant recipients are white, well-educated, married men.

With regard to medical considerations, we found that the mean length of time between the diagnosis of heart disease and transplantation was 5.4 years. The longest living heart transplant recipient in the study received their heart transplant nearly 14 years ago, although the majority of patients have had their transplant two years or less. Coronary artery disease and cardiomyopathy are the two leading indications for heart transplantation. We found that there were more deceased patients with contraindications to heart transplantation than living patients. The majority of patients had NYHA Class IV heart disease at the time they received their transplant. The majority of living heart transplant recipients now have Class I status. Among the living transplant recipients, about

half are on cyclosporine for immunosuppression compared with 14 percent of the deceased patients at the time of their death. Not surprisingly, infections are common among heart transplant recipients. The most common among living recipients are herpes simplex and cytomegalovirus. Living heart transplant recipients experienced an average of 2.46 rejection episodes, although 17 of the living recipients had not experienced a single rejection episode. Histocompatibility findings are not conclusive. Only 3 living recipients were known to have a positive lymphocyte crossmatch when they received their transplant. The most HLA antigens any patient matched with their donor on is 6. We did find that heart transplant recipients develop comorbidity subsequent to transplantation. Among living heart transplant recipients, the leading comorbid condition developing posttransplant was osteoporosis followed by diabetes and vision disorders.

There are many social and family considerations relevant to the heart transplant experience. In general, we found that heart transplant recipients had close family and social relationships, which is not surprising since social support is of primary importance as a patient selection criterion. Most patients appear to have adjusted quite well to their transplant, although many indicated that the transplant has been a source of concern and problems. However, half the living recipients noted that they were "very happy" these days. Most patients appeared to be realistic in their assessment of their health status and their level of physical functioning is consistent with their health status evaluations. About 30 percent of the patients indicated that they enjoyed nonstrenuous activities during

the course of a week. Forty percent of the patients characterized themselves as "not very active, sitting and walking mostly." Half of the patients said they are now doing most of the things they were doing before their illness, but even so, 50 percent of the patients said they were unable to work because of their health. Approximately 30 percent of the recipients of heart transplants are currently working.

Many patients have concerns related to finances, although the household income of the majority of patients is $15,000 or more. Nearly two-thirds of the patients currently receive Social Security retirement or disability benefits and another 17 percent receive union or employer disability benefits. While private insurers have helped transplant recipients meet their medical expenses, nearly 70 percent of all patients indicated that they still have out-of-pocket expenses. About 60 percent of the patients indicated that they were extremely or moderately concerned about finances.

Based on the foregoing there is much to conclude about the varied experiences of heart transplant recipients. It is beyond the scope of this chapter to draw all the appropriate conclusions since subsequent chapters in this report will elaborate on a variety of subjects that have been highlighted above. Also, depending upon one's perspective, different conclusions may be drawn from these results. For this reason, we refrain from drawing conclusions beyond those stated in the text of the Chapter.

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